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(54) **SPINOUS PROCESS IMPLANTS AND ASSOCIATED METHODS**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,774,350	A	12/1956	Cleveland, Jr.
3,242,922	A	3/1966	Thomas
3,648,691	A	3/1972	Lumb et al.
4,269,178	A	5/1981	Keene
4,274,401	A	6/1981	Miskew
4,369,769	A	1/1983	Edwards

(Continued)

FOREIGN PATENT DOCUMENTS

CN	101129271	A	2/2008
JP	2003523214	A	8/2003

(Continued)

OTHER PUBLICATIONS

International Bureau, Notification Concerning Transmittal of International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) May 14, 2010.

(Continued)

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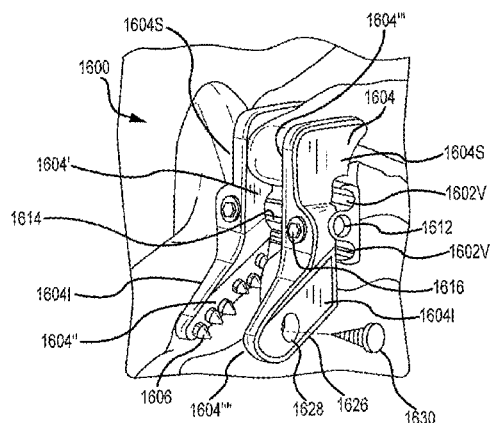
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(57)

ABSTRACT

The present invention provides spinous process implant and associated methods. In one aspect of the invention the implant limits the maximum spacing between the spinous processes. In another aspect of the invention, a spacer has at least one transverse opening to facilitate tissue in-growth. In another aspect of the invention, an implant includes a spacer and separate extensions engageable with the spacer. In another aspect of the invention, instrumentation for inserting the implant is provided. In other aspects of the invention, methods for treating spine disease are provided.

25 Claims, 26 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,554,914	A	11/1985	Kapp et al.	7,048,736	B2	5/2006	Robinson et al.
4,570,618	A	2/1986	Wu	7,087,083	B2	8/2006	Pasquet et al.
4,573,454	A	3/1986	Hoffman	7,101,375	B2	9/2006	Zucherman et al.
4,697,582	A	10/1987	William	7,131,972	B2	11/2006	Mazda et al.
4,773,402	A	9/1988	Asher et al.	7,163,558	B2	1/2007	Senegas et al.
5,007,909	A	4/1991	Rogozinski	7,189,234	B2	3/2007	Zucherman et al.
5,011,484	A	4/1991	Breard	7,201,751	B2	4/2007	Zucherman et al.
5,030,220	A	7/1991	Howland	7,238,204	B2	7/2007	Le Couedic et al.
5,306,275	A	4/1994	Bryan	7,306,628	B2	12/2007	Zucherman et al.
5,413,576	A	5/1995	Rivard	7,335,203	B2	2/2008	Winslow et al.
5,496,318	A	3/1996	Howland et al.	7,458,981	B2	12/2008	Fielding et al.
5,527,312	A	6/1996	Ray	7,473,268	B2	1/2009	Zucherman et al.
5,540,703	A	7/1996	Barker, Jr. et al.	7,476,251	B2	1/2009	Zucherman et al.
5,609,634	A	3/1997	Voydeville	7,481,839	B2	1/2009	Zucherman et al.
5,628,756	A	5/1997	Barker, Jr. et al.	7,510,567	B2	3/2009	Zucherman et al.
5,645,599	A	7/1997	Samani	7,520,887	B2	4/2009	Maxy et al.
5,702,452	A	12/1997	Argenson et al.	7,530,991	B2	5/2009	Nekozyuka et al.
5,725,582	A	3/1998	Bevan et al.	7,537,613	B2	5/2009	Armin et al.
5,836,948	A	11/1998	Zucherman et al.	7,549,999	B2	6/2009	Zucherman et al.
5,860,977	A	1/1999	Zucherman et al.	7,585,313	B2	9/2009	Kwak et al.
5,876,404	A	3/1999	Zucherman et al.	7,585,316	B2	9/2009	Trieu
5,928,232	A	7/1999	Howland et al.	7,588,592	B2	9/2009	Winslow et al.
5,989,256	A	11/1999	Kuslich et al.	7,621,939	B2	11/2009	Zucherman et al.
6,048,342	A	4/2000	Zucherman et al.	7,635,377	B2	12/2009	Zucherman et al.
6,068,630	A	5/2000	Zucherman et al.	7,635,378	B2	12/2009	Zucherman et al.
6,074,390	A	6/2000	Zucherman et al.	7,637,912	B2	12/2009	Iwasaki et al.
6,090,112	A	7/2000	Zucherman et al.	7,658,752	B2	2/2010	Labrom et al.
6,099,527	A	8/2000	Hochschuler et al.	7,871,426	B2 *	1/2011	Chin et al. 606/248
6,132,464	A	10/2000	Martin	7,922,750	B2	4/2011	Trautwein et al.
6,149,652	A	11/2000	Zucherman et al.	7,955,392	B2 *	6/2011	Dewey et al. 623/17.16
6,152,926	A	11/2000	Zucherman et al.	8,167,915	B2	5/2012	Ferree et al.
6,156,038	A	12/2000	Zucherman et al.	2001/0007073	A1	7/2001	Zucherman et al.
6,183,471	B1	2/2001	Zucherman et al.	2001/0016743	A1	8/2001	Zucherman et al.
6,190,387	B1	2/2001	Zucherman et al.	2001/0016776	A1	8/2001	Zuckerman et al.
6,235,030	B1	5/2001	Zucherman et al.	2001/0021850	A1	9/2001	Zucherman et al.
6,235,059	B1 *	5/2001	Benezech et al. 623/17.16	2001/0039452	A1	11/2001	Zucherman et al.
6,238,397	B1	5/2001	Zucherman et al.	2002/0045899	A1 *	4/2002	Errico et al. 606/61
6,280,444	B1	8/2001	Zucherman et al.	2002/0116000	A1 *	8/2002	Zucherman et al. 606/61
6,312,431	B1	11/2001	Asfora	2002/0143331	A1	10/2002	Zucherman et al.
6,332,882	B1	12/2001	Zucherman et al.	2002/0183746	A1	12/2002	Zucherman et al.
6,332,883	B1	12/2001	Zucherman et al.	2003/0040746	A1	2/2003	Mitchell et al.
6,340,362	B1 *	1/2002	Pierer et al. 606/71	2003/0065330	A1	4/2003	Zucherman et al.
6,364,883	B1	4/2002	Santilli	2003/0216736	A1	11/2003	Robinson et al.
6,379,355	B1	4/2002	Zucherman et al.	2003/0220643	A1	11/2003	Ferree
6,416,776	B1	7/2002	Shamie	2004/0097931	A1	5/2004	Mitchell
6,419,676	B1	7/2002	Zucherman et al.	2004/0153071	A1	8/2004	Zucherman et al.
6,419,677	B2	7/2002	Zucherman et al.	2004/0162617	A1	8/2004	Zucherman et al.
6,440,169	B1	8/2002	Elberg et al.	2004/0167520	A1	8/2004	Zucherman et al.
6,451,019	B1	9/2002	Zucherman et al.	2004/0167521	A1 *	8/2004	De Windt 606/69
6,451,020	B1	9/2002	Zucherman et al.	2004/0193159	A1	9/2004	Zucherman et al.
6,478,796	B2	11/2002	Zucherman et al.	2004/0220568	A1	11/2004	Zucherman et al.
6,500,178	B2	12/2002	Zucherman et al.	2004/0249379	A1	12/2004	Winslow et al.
6,514,255	B1	2/2003	Ferree	2005/0010293	A1	1/2005	Zucherman et al.
6,514,256	B2	2/2003	Zucherman et al.	2005/0010298	A1	1/2005	Zucherman et al.
6,582,433	B2	6/2003	Yun	2005/0075634	A1	4/2005	Zucherman et al.
6,589,243	B1	7/2003	Viart et al.	2005/0085855	A1 *	4/2005	Forsberg 606/213
6,626,944	B1	9/2003	Taylor	2005/0101955	A1	5/2005	Zucherman et al.
6,652,527	B2	11/2003	Zucherman et al.	2005/0143738	A1	6/2005	Zucherman et al.
6,652,534	B2	11/2003	Zucherman et al.	2005/0143827	A1	6/2005	Globerman et al.
6,656,185	B2	12/2003	Gleason et al.	2005/0165398	A1	7/2005	Reiley
6,669,729	B2	12/2003	Chin	2005/0192574	A1	9/2005	Blain
6,682,563	B2 *	1/2004	Scharf 623/17.16	2005/0196420	A1	9/2005	Zucherman et al.
6,695,842	B2	2/2004	Zucherman et al.	2005/0203512	A1	9/2005	Hawkins et al.
6,699,246	B2	3/2004	Zucherman et al.	2005/0203624	A1	9/2005	Serhan et al.
6,699,247	B2	3/2004	Zucherman et al.	2005/0209603	A1	9/2005	Zucherman et al.
6,712,819	B2	3/2004	Zucherman et al.	2005/0228383	A1	10/2005	Zucherman et al.
6,733,534	B2	5/2004	Sherman	2005/0228384	A1	10/2005	Zucherman et al.
6,761,720	B1	7/2004	Senegas	2005/0234452	A1 *	10/2005	Malandain 606/61
6,796,983	B1	9/2004	Zucherman et al.	2005/0240182	A1	10/2005	Zucherman et al.
6,835,205	B2	12/2004	Atkinson et al.	2005/0245929	A1	11/2005	Winslow et al.
6,902,566	B2	6/2005	Zucherman et al.	2005/0245937	A1	11/2005	Winslow
6,902,580	B2	6/2005	Fallin et al.	2005/0261768	A1	11/2005	Trieu
6,926,728	B2	8/2005	Zucherman et al.	2005/0283237	A1	12/2005	Zucherman et al.
6,946,000	B2	9/2005	Senegas et al.	2005/0283242	A1	12/2005	Zucherman et al.
7,029,473	B2	4/2006	Zucherman et al.	2005/0283243	A1	12/2005	Zucherman et al.
				2005/0288672	A1	12/2005	Ferree
				2006/0004447	A1	1/2006	Mastorrio et al.
				2006/0015181	A1	1/2006	Elberg
				2006/0036246	A1	2/2006	Carl et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2006/0036258	A1	2/2006	Zucherman et al.	2007/0185490	A1	8/2007	Implicito
2006/0036259	A1	2/2006	Carl et al.	2007/0191833	A1	8/2007	Bruneau et al.
2006/0036324	A1	2/2006	Sachs et al.	2007/0191834	A1	8/2007	Bruneau et al.
2006/0058790	A1	3/2006	Carl et al.	2007/0191837	A1	8/2007	Trieu
2006/0064165	A1	3/2006	Zucherman et al.	2007/0191838	A1	8/2007	Bruneau et al.
2006/0064166	A1	3/2006	Zucherman et al.	2007/0191847	A1	8/2007	Arnin et al.
2006/0084983	A1	4/2006	Kim	2007/0191947	A1	8/2007	Arnin et al.
2006/0084985	A1	4/2006	Kim	2007/0191948	A1	8/2007	Arnin et al.
2006/0084988	A1	4/2006	Kim	2007/0191949	A1	8/2007	Arnin et al.
2006/0084994	A1	4/2006	Atkinson et al.	2007/0191950	A1	8/2007	Arnin et al.
2006/0085069	A1	4/2006	Kim	2007/0203491	A1	8/2007	Pasquet et al.
2006/0085070	A1	4/2006	Kim	2007/0203493	A1	8/2007	Zucherman et al.
2006/0089654	A1	4/2006	Lins et al.	2007/0203494	A1	8/2007	Arnin et al.
2006/0089718	A1	4/2006	Zucherman et al.	2007/0203495	A1	8/2007	Zucherman et al.
2006/0106381	A1	5/2006	Ferree et al.	2007/0203496	A1	8/2007	Zucherman et al.
2006/0106397	A1	5/2006	Lins	2007/0203497	A1	8/2007	Zucherman et al.
2006/0122606	A1*	6/2006	Wolgen 606/71	2007/0203501	A1	8/2007	Zucherman et al.
2006/0122620	A1	6/2006	Kim	2007/0208347	A1	9/2007	Zucherman et al.
2006/0136060	A1	6/2006	Taylor	2007/0213724	A1	9/2007	Arnin et al.
2006/0161154	A1	7/2006	McAfee	2007/0213829	A1	9/2007	Le Couedic et al.
2006/0184247	A1	8/2006	Edidin et al.	2007/0219552	A1	9/2007	Zucherman et al.
2006/0184248	A1	8/2006	Edidin et al.	2007/0225706	A1	9/2007	Clark et al.
2006/0195102	A1	8/2006	Malandain	2007/0225724	A1	9/2007	Edmond
2006/0217726	A1	9/2006	Maxy et al.	2007/0225807	A1	9/2007	Phan et al.
2006/0224159	A1	10/2006	Anderson	2007/0233068	A1	10/2007	Bruneau et al.
2006/0235387	A1	10/2006	Peterman	2007/0233074	A1	10/2007	Anderson et al.
2006/0235521	A1	10/2006	Zucherman et al.	2007/0233076	A1	10/2007	Trieu
2006/0241601	A1	10/2006	Trautwein et al.	2007/0233077	A1	10/2007	Khalili
2006/0241610	A1	10/2006	Lim et al.	2007/0233081	A1	10/2007	Pasquet et al.
2006/0241757	A1	10/2006	Anderson	2007/0233082	A1	10/2007	Chin et al.
2006/0247623	A1	11/2006	Anderson et al.	2007/0233083	A1	10/2007	Abdou
2006/0247634	A1	11/2006	Warner et al.	2007/0233088	A1	10/2007	Edmond
2006/0247640	A1	11/2006	Blackwell et al.	2007/0233096	A1	10/2007	Garcia-Bengochea
2006/0259037	A1	11/2006	Hartmann et al.	2007/0233098	A1	10/2007	Mastrorio et al.
2006/0264938	A1	11/2006	Zucherman et al.	2007/0233129	A1	10/2007	Bertagnoli et al.
2006/0264939	A1	11/2006	Zucherman et al.	2007/0250060	A1	10/2007	Anderson et al.
2006/0265066	A1	11/2006	Zucherman et al.	2007/0260245	A1	11/2007	Malandain et al.
2006/0265067	A1	11/2006	Zucherman et al.	2007/0265623	A1	11/2007	Malandain et al.
2006/0271049	A1	11/2006	Zucherman et al.	2007/0265624	A1	11/2007	Zucherman et al.
2006/0271055	A1	11/2006	Thramann	2007/0265625	A1	11/2007	Zucherman et al.
2006/0271194	A1*	11/2006	Zucherman et al. 623/17.11	2007/0270812	A1	11/2007	Peckham
2006/0293662	A1	12/2006	Boyer, II et al.	2007/0270823	A1	11/2007	Trieu et al.
2007/0005064	A1	1/2007	Anderson et al.	2007/0270824	A1	11/2007	Lim et al.
2007/0010813	A1	1/2007	Zucherman et al.	2007/0270825	A1	11/2007	Carls et al.
2007/0016303	A1	1/2007	Jackson	2007/0270826	A1	11/2007	Trieu et al.
2007/0032790	A1	2/2007	Aschmann et al.	2007/0270827	A1	11/2007	Lim et al.
2007/0043361	A1	2/2007	Malandain et al.	2007/0270828	A1	11/2007	Bruneau et al.
2007/0043362	A1	2/2007	Malandain et al.	2007/0270829	A1	11/2007	Carls et al.
2007/0043363	A1	2/2007	Malandain et al.	2007/0270834	A1	11/2007	Bruneau et al.
2007/0049934	A1	3/2007	Edidin et al.	2007/0270840	A1	11/2007	Chin et al.
2007/0049935	A1	3/2007	Edidin et al.	2007/0272259	A1	11/2007	Allard et al.
2007/0055237	A1	3/2007	Edidin et al.	2007/0276368	A1	11/2007	Trieu et al.
2007/0055246	A1	3/2007	Zucherman et al.	2007/0276370	A1	11/2007	Altarac et al.
2007/0073292	A1	3/2007	Kohm et al.	2007/0276372	A1	11/2007	Malandain et al.
2007/0093823	A1	4/2007	Booth et al.	2007/0276373	A1	11/2007	Malandain
2007/0093825	A1	4/2007	Ferree et al.	2007/0276381	A1	11/2007	Butler et al.
2007/0093828	A1	4/2007	Abdou	2007/0276493	A1	11/2007	Malandain et al.
2007/0093830	A1	4/2007	Zucherman et al.	2007/0276496	A1	11/2007	Lange et al.
2007/0100340	A1	5/2007	Lange et al.	2007/0276497	A1	11/2007	Anderson
2007/0106298	A1	5/2007	Carli et al.	2007/0276500	A1	11/2007	Zucherman et al.
2007/0106385	A1	5/2007	Zucherman et al.	2007/0282340	A1	12/2007	Malandain
2007/0118120	A1	5/2007	Stevenson et al.	2007/0282442	A1	12/2007	Malandain et al.
2007/0123861	A1	5/2007	Dewey et al.	2007/0282443	A1	12/2007	Globerman et al.
2007/0142915	A1	6/2007	Altarac et al.	2007/0288006	A1	12/2007	Arnin et al.
2007/0149972	A1	6/2007	Nakajima et al.	2007/0299526	A1	12/2007	Malandain
2007/0161993	A1	7/2007	Lowery et al.	2008/0004706	A1	1/2008	Arnin et al.
2007/0162000	A1	7/2007	Perkins	2008/0009947	A1	1/2008	Arnin et al.
2007/0162001	A1	7/2007	Chin et al.	2008/0009948	A1	1/2008	Arnin et al.
2007/0162005	A1	7/2007	Peterson et al.	2008/0015609	A1	1/2008	Trautwein et al.
2007/0167945	A1	7/2007	Lange et al.	2008/0015693	A1	1/2008	Le Couedic
2007/0173818	A1	7/2007	Hestad et al.	2008/0015700	A1	1/2008	Zucherman et al.
2007/0173821	A1	7/2007	Trieu	2008/0021460	A1	1/2008	Bruneau et al.
2007/0173823	A1	7/2007	Dewey et al.	2008/0021468	A1	1/2008	Zucherman et al.
2007/0173832	A1	7/2007	Tebbe et al.	2008/0021471	A1	1/2008	Winslow et al.
2007/0179500	A1	8/2007	Chin et al.	2008/0021560	A1	1/2008	Zucherman et al.
				2008/0021561	A1	1/2008	Zucherman et al.
				2008/0027433	A1	1/2008	Kohm et al.
				2008/0027434	A1	1/2008	Zucherman et al.
				2008/0027435	A1	1/2008	Zucherman et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2008/0027438	A1	1/2008	Abdou	2008/0177306	A1	7/2008	Lamborne et al.
2008/0027545	A1	1/2008	Zucherman et al.	2008/0177312	A1	7/2008	Perez-Cruet et al.
2008/0027552	A1	1/2008	Zucherman et al.	2008/0177391	A1	7/2008	Mitchell et al.
2008/0027553	A1	1/2008	Zucherman et al.	2008/0183210	A1	7/2008	Zucherman et al.
2008/0033445	A1	2/2008	Zucherman et al.	2008/0183211	A1	7/2008	Lamborne et al.
2008/0033552	A1	2/2008	Lee et al.	2008/0183218	A1	7/2008	Mueller et al.
2008/0033553	A1	2/2008	Zucherman et al.	2008/0195152	A1	8/2008	Altarac et al.
2008/0033558	A1	2/2008	Zucherman et al.	2008/0208344	A1	8/2008	Kilpela et al.
2008/0033559	A1	2/2008	Zucherman et al.	2008/0215058	A1	9/2008	Zucherman et al.
2008/0033560	A1	2/2008	Zucherman et al.	2008/0221692	A1	9/2008	Zucherman et al.
2008/0039853	A1	2/2008	Zucherman et al.	2008/0228225	A1	9/2008	Trautwein et al.
2008/0039858	A1	2/2008	Zucherman et al.	2008/0234733	A1	9/2008	Scrantz et al.
2008/0039859	A1	2/2008	Zucherman et al.	2008/0234735	A1	9/2008	Joshi
2008/0039944	A1	2/2008	Malandain et al.	2008/0234824	A1	9/2008	Youssef et al.
2008/0039945	A1	2/2008	Zucherman et al.	2008/0243186	A1	10/2008	Abdou
2008/0039946	A1	2/2008	Zucherman et al.	2008/0243250	A1	10/2008	Seifert et al.
2008/0039947	A1	2/2008	Zucherman et al.	2008/0249528	A1	10/2008	Khalife
2008/0045958	A1	2/2008	Zucherman et al.	2008/0249622	A1 *	10/2008	Gray 623/17.11
2008/0045959	A1	2/2008	Zucherman et al.	2008/0255616	A1	10/2008	Atkinson et al.
2008/0046081	A1	2/2008	Zucherman et al.	2008/0255668	A1	10/2008	Fallin et al.
2008/0046085	A1	2/2008	Zucherman et al.	2008/0255669	A1	10/2008	Fallin et al.
2008/0046086	A1	2/2008	Zucherman et al.	2008/0262617	A1	10/2008	Froehlich et al.
2008/0046087	A1	2/2008	Zucherman et al.	2008/0262619	A1	10/2008	Ray
2008/0046088	A1	2/2008	Zucherman et al.	2008/0269904	A1 *	10/2008	Voorhies 623/17.16
2008/0051785	A1	2/2008	Zucherman et al.	2008/0281359	A1	11/2008	Abdou
2008/0051891	A1	2/2008	Malandain et al.	2008/0281360	A1	11/2008	Vittur et al.
2008/0051892	A1	2/2008	Malandain et al.	2008/0281361	A1	11/2008	Vittur et al.
2008/0051893	A1	2/2008	Malandain et al.	2008/0281423	A1	11/2008	Sheffer et al.
2008/0051894	A1	2/2008	Malandain et al.	2008/0287997	A1	11/2008	Altarac et al.
2008/0051895	A1	2/2008	Malandain et al.	2008/0288072	A1	11/2008	Kohm
2008/0051896	A1	2/2008	Suddaby	2008/0288075	A1	11/2008	Zucherman et al.
2008/0051898	A1	2/2008	Zucherman et al.	2008/0288078	A1	11/2008	Kohm et al.
2008/0051899	A1	2/2008	Zucherman et al.	2008/0294199	A1	11/2008	Kohm et al.
2008/0051904	A1	2/2008	Zucherman et al.	2008/0294200	A1	11/2008	Kohm et al.
2008/0051905	A1	2/2008	Zucherman et al.	2008/0294204	A1 *	11/2008	Chirico et al. 606/327
2008/0051906	A1	2/2008	Malandain et al.	2008/0294263	A1	11/2008	Altarac et al.
2008/0058806	A1	3/2008	Klyce et al.	2008/0300686	A1	12/2008	Khoo
2008/0058807	A1	3/2008	Klyce et al.	2008/0300687	A1	12/2008	Lin et al.
2008/0058808	A1	3/2008	Klyce et al.	2008/0312741	A1	12/2008	Lee et al.
2008/0058934	A1	3/2008	Malandain et al.	2008/0319549	A1	12/2008	Greenhalgh et al.
2008/0058935	A1	3/2008	Malandain et al.	2008/0319550	A1	12/2008	Altarac et al.
2008/0058936	A1	3/2008	Malandain et al.	2009/0005819	A1	1/2009	Ben-Mokhtar et al.
2008/0058937	A1	3/2008	Malandain et al.	2009/0005873	A1	1/2009	Slivka et al.
2008/0058941	A1	3/2008	Zucherman et al.	2009/0012528	A1	1/2009	Aschmann et al.
2008/0065086	A1	3/2008	Zucherman et al.	2009/0012614	A1	1/2009	Dixon
2008/0065212	A1	3/2008	Zucherman et al.	2009/0018658	A1	1/2009	Garcia
2008/0065213	A1	3/2008	Zucherman et al.	2009/0018662	A1	1/2009	Pasquet et al.
2008/0065214	A1	3/2008	Zucherman et al.	2009/0030523	A1	1/2009	Taylor
2008/0071280	A1	3/2008	Winslow	2009/0036925	A1	2/2009	Sala et al.
2008/0071376	A1	3/2008	Kohm et al.	2009/0043342	A1	2/2009	Freedland
2008/0071378	A1	3/2008	Zucherman et al.	2009/0054931	A1	2/2009	Metz-Stavenhagen
2008/0071380	A1	3/2008	Sweeney	2009/0054988	A1	2/2009	Hess
2008/0082118	A1	4/2008	Edidin et al.	2009/0062915	A1	3/2009	Kohm et al.
2008/0082167	A1	4/2008	Edidin et al.	2009/0062918	A1	3/2009	Wang et al.
2008/0082172	A1	4/2008	Jackson	2009/0082808	A1	3/2009	Butler et al.
2008/0086212	A1	4/2008	Zucherman et al.	2009/0093817	A1	4/2009	Zucherman et al.
2008/0108990	A1	5/2008	Mitchell et al.	2009/0093843	A1	4/2009	Lemoine et al.
2008/0109082	A1	5/2008	Fink et al.	2009/0093883	A1	4/2009	Carrasco
2008/0114358	A1	5/2008	Anderson et al.	2009/0099603	A1	4/2009	Nishida
2008/0114455	A1	5/2008	Lange et al.	2009/0105761	A1	4/2009	Robie
2008/0114456	A1	5/2008	Dewey et al.	2009/0105773	A1	4/2009	Lange et al.
2008/0132952	A1	6/2008	Malandain et al.	2009/0112266	A1	4/2009	Weng et al.
2008/0140125	A1	6/2008	Mitchell et al.	2009/0118833	A1	5/2009	Hudgins et al.
2008/0147190	A1	6/2008	Dewey et al.	2009/0138045	A1	5/2009	Ciupik et al.
2008/0147192	A1	6/2008	Edidin et al.	2009/0138046	A1	5/2009	Altarac et al.
2008/0161818	A1	7/2008	Kloss et al.	2009/0138087	A1	5/2009	Miglietta et al.
2008/0161822	A1	7/2008	Perez-Cruet et al.	2009/0149885	A1	6/2009	Durward et al.
2008/0161856	A1	7/2008	Liu et al.	2009/0149886	A1	6/2009	Zentes et al.
2008/0167655	A1	7/2008	Wang et al.	2009/0171399	A1 *	7/2009	White et al. 606/286
2008/0167656	A1	7/2008	Zucherman et al.	2009/0198241	A1	8/2009	Phan
2008/0167657	A1	7/2008	Greenhalgh	2009/0198277	A1	8/2009	Gordon et al.
2008/0172057	A1	7/2008	Zucherman et al.	2009/0198278	A1	8/2009	Shibata et al.
2008/0177271	A1	7/2008	Yeh	2009/0198337	A1	8/2009	Phan
2008/0177272	A1	7/2008	Zucherman et al.	2009/0198338	A1	8/2009	Phan
2008/0177298	A1	7/2008	Zucherman et al.	2009/0209965	A1	8/2009	Lewis
				2009/0216274	A1	8/2009	Morancy-Meister et al.
				2009/0222043	A1	9/2009	Altarac et al.
				2009/0234389	A1	9/2009	Chuang et al.
				2009/0240280	A1	9/2009	Wang et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0240283	A1	9/2009	Carls et al.	
2009/0248076	A1	10/2009	Reynolds et al.	
2009/0248079	A1	10/2009	Kwak et al.	
2009/0248081	A1	10/2009	LeHuec et al.	
2009/0254122	A1	10/2009	Khalife	
2009/0254185	A1	10/2009	Dollinger	
2009/0259316	A1	10/2009	Ginn et al.	
2009/0265006	A1	10/2009	Seifert et al.	
2009/0270919	A1	10/2009	Dos Reis, Jr.	
2009/0275982	A1	11/2009	Taylor	
2009/0281626	A1	11/2009	Farr	
2009/0292314	A1	11/2009	Mangione et al.	
2009/0292315	A1	11/2009	Trieu	
2009/0292316	A1	11/2009	Hess	
2009/0292317	A1	11/2009	Belliard	
2009/0297603	A1	12/2009	Joshi	
2009/0306715	A1	12/2009	Jackson et al.	
2009/0306716	A1	12/2009	Beger et al.	
2009/0318967	A1	12/2009	Jeon et al.	
2009/0326581	A1	12/2009	Galley et al.	
2010/0004688	A1	1/2010	Maas et al.	
2010/0004744	A1	1/2010	Zucherman et al.	
2010/0010546	A1	1/2010	Hermida Ochoa	
2010/0036419	A1	2/2010	Patel et al.	
2010/0191287	A1 *	7/2010	Bucci	606/249
2010/0222817	A1	9/2010	Perez-Cruet et al.	
2011/0172711	A1 *	7/2011	Kirschman	606/252
2011/0313458	A1 *	12/2011	Butler et al.	606/249

FOREIGN PATENT DOCUMENTS

KR	20060124851	A	12/2006
WO	03099147	A1	12/2003
WO	WO-2004039239	A2	5/2004
WO	WO-2005055868	A2	6/2005
WO	2006119235	A1	11/2006
WO	WO-2007019391	A2	2/2007
WO	WO-2008067452	A1	6/2008
WO	WO-2008088613	A2	7/2008

OTHER PUBLICATIONS

Notification of Transmittal of International Preliminary Report on Patentability Apr. 5, 2010.

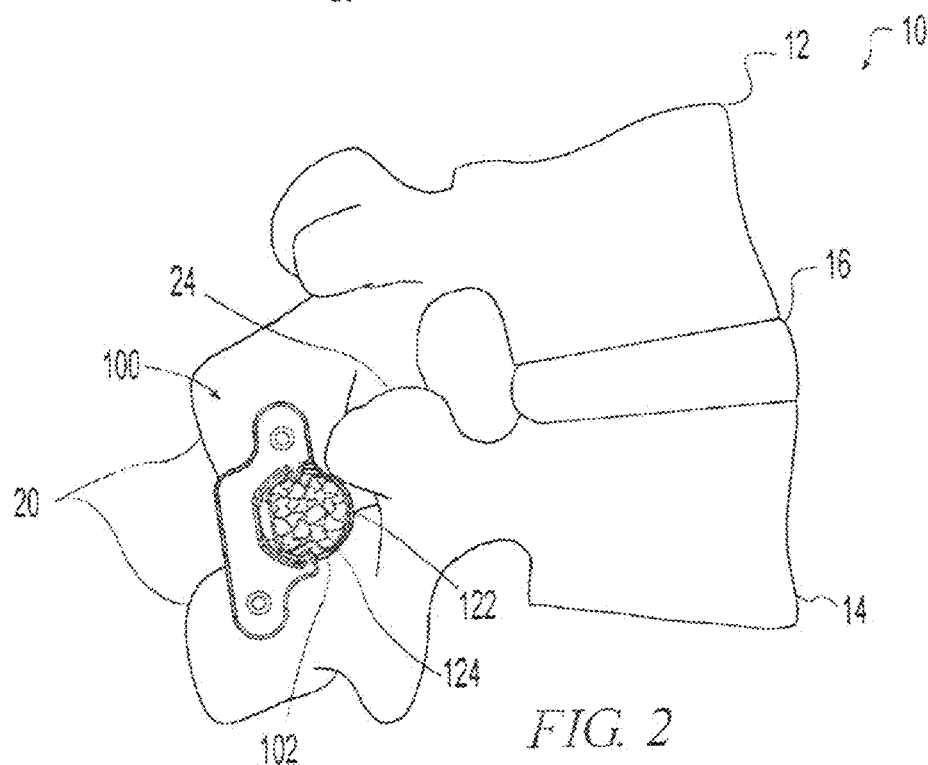
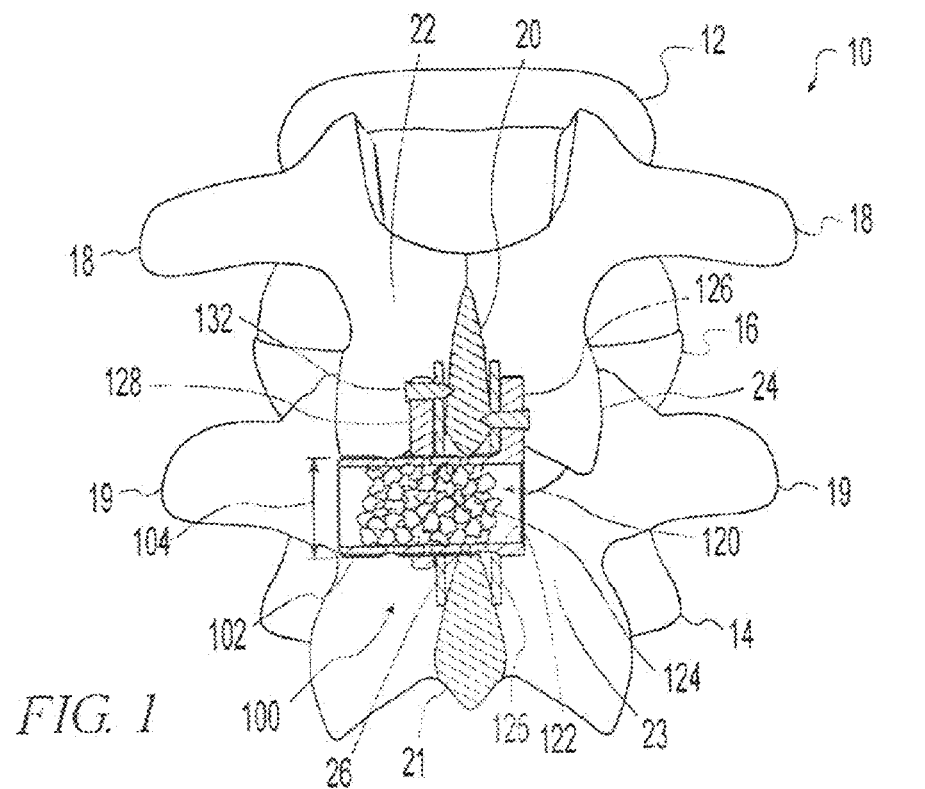
Notice of Reasons for Rejection (English Translation) for Japanese Patent Application No. 2010-532090, issued by the Japan Patent Office on Sep. 24, 2013. 3 pages.

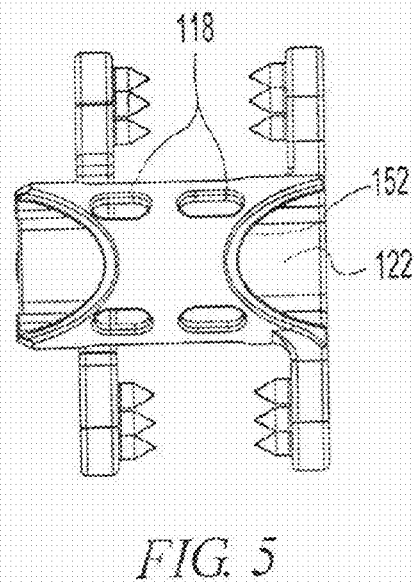
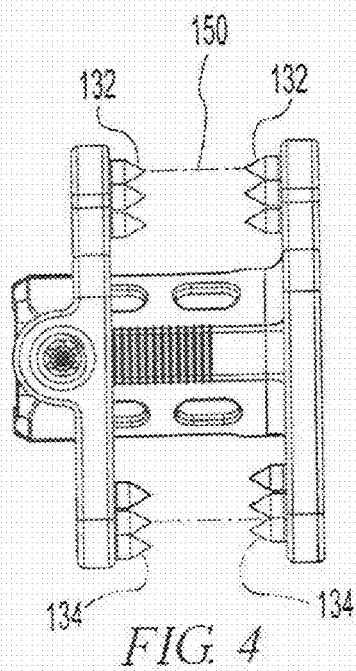
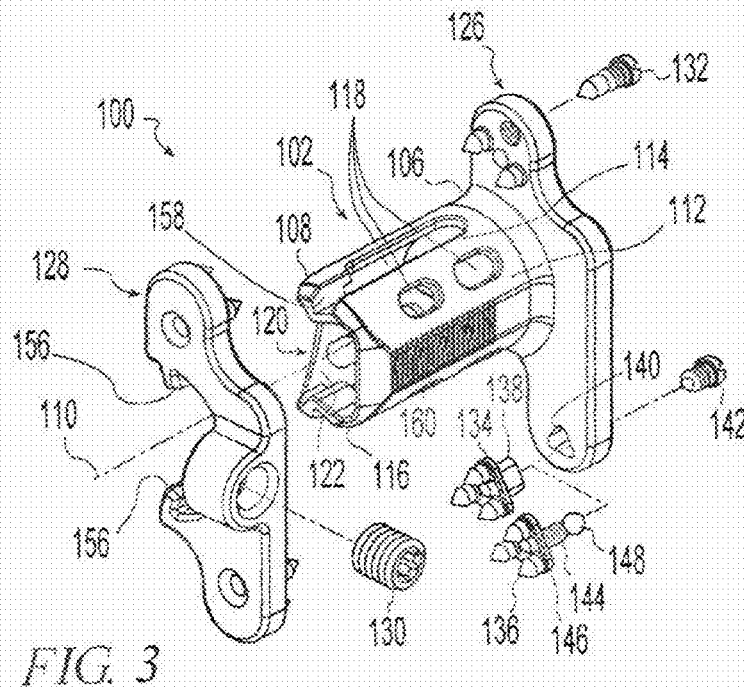
European Search Report for European Patent Application No. 10759359.2, issued by the European Patent Office on Nov. 26, 2013. 6 pages.

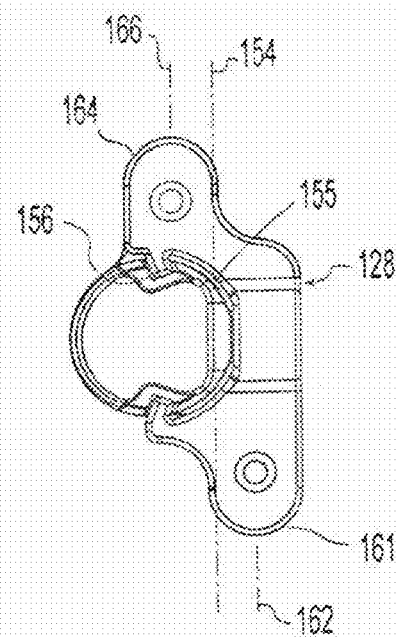
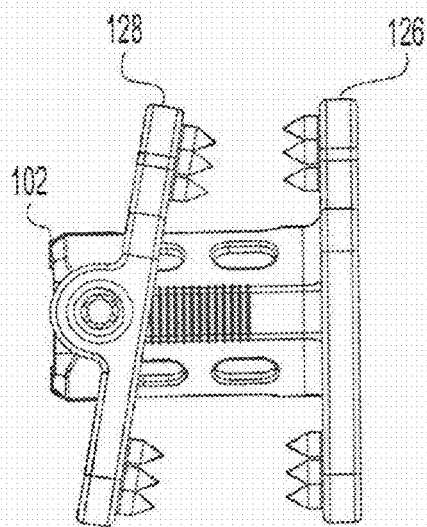
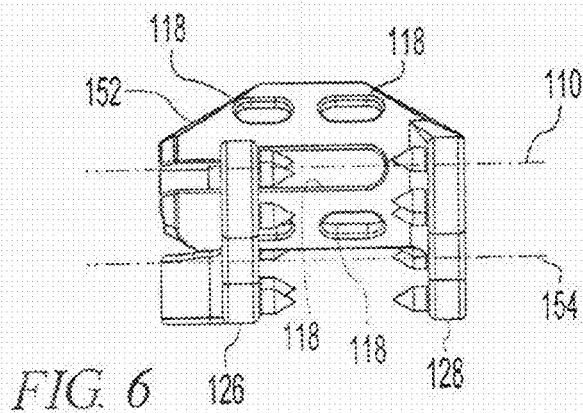
European Search Report for European Patent Application No. 13180855.2, issued by the European Patent Office on Oct. 7, 2013. 4 pages.

Defendant Pioneer Surgical Technology, Inc.'s Invalidity Contentions filed Jul. 31, 2013 in the U.S. District Court for the District of Colorado, Civil Action No. 1:13-cv-01035-WJM-BNB, 27 pages.

* cited by examiner







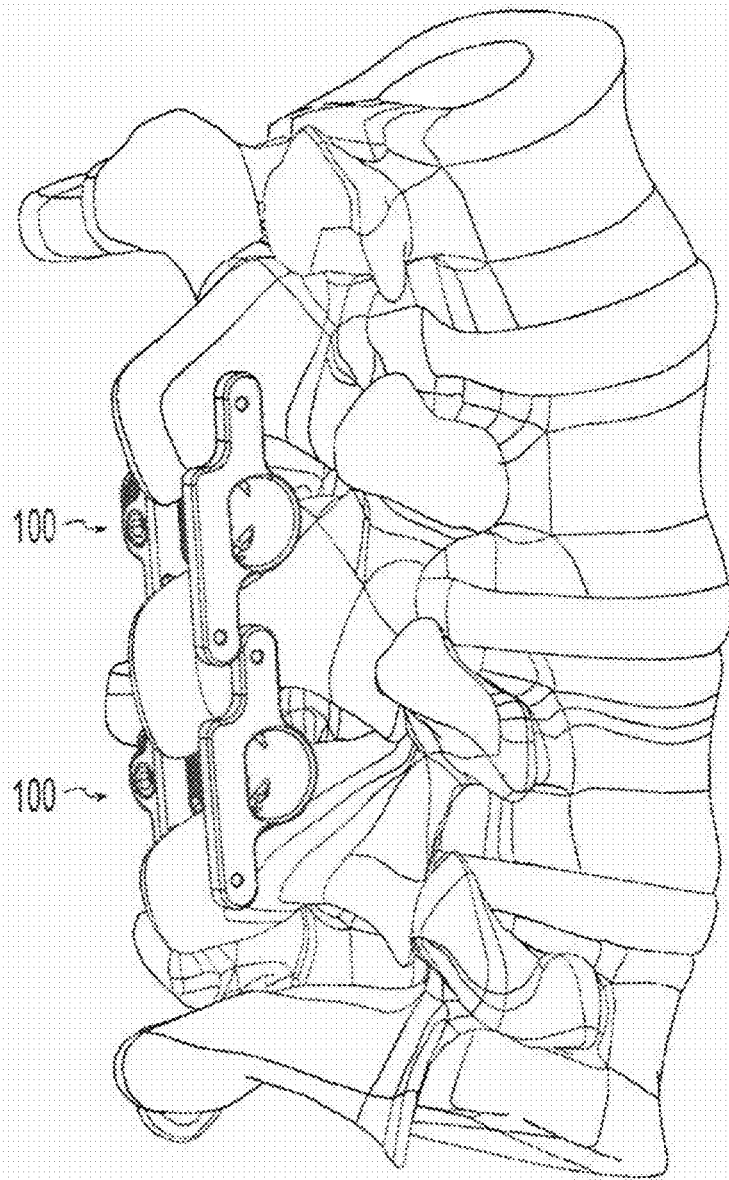


FIG. 9

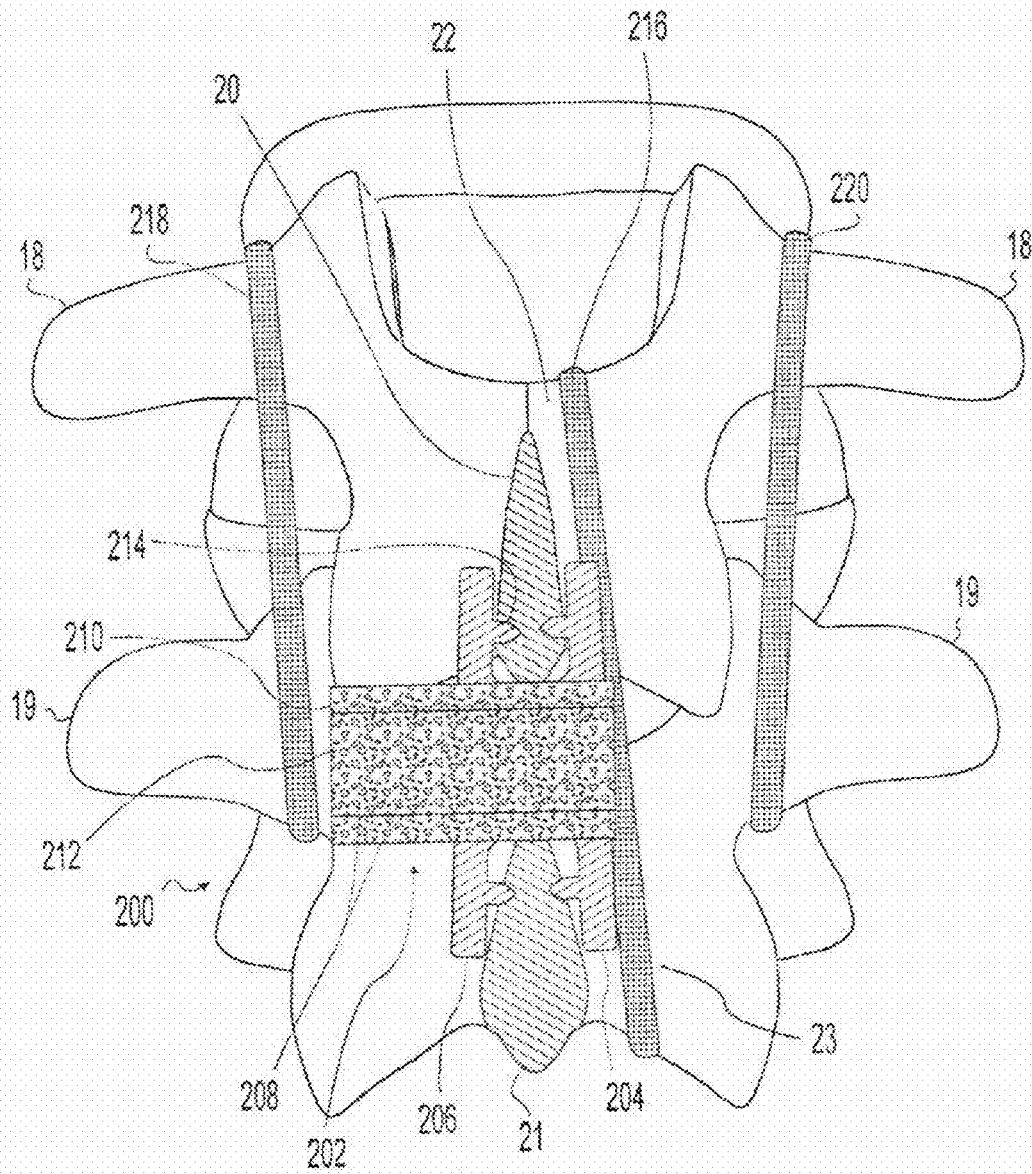
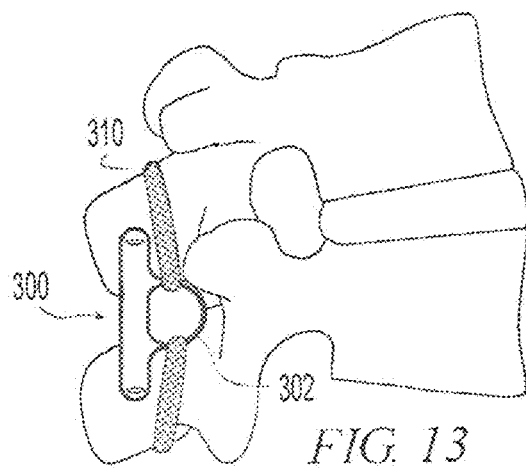
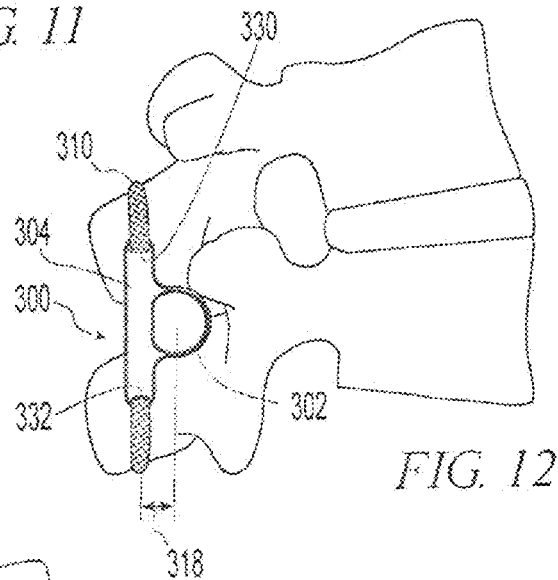
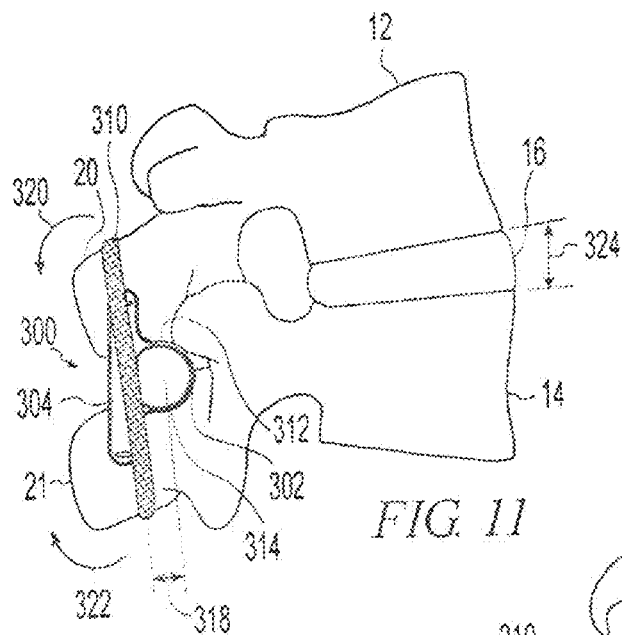


FIG. 10



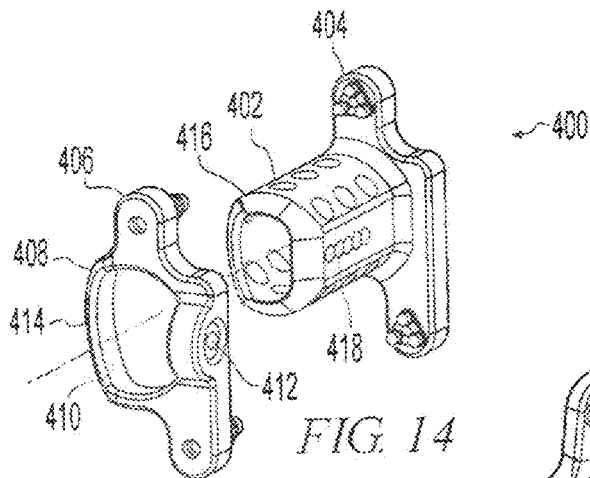


FIG. 14

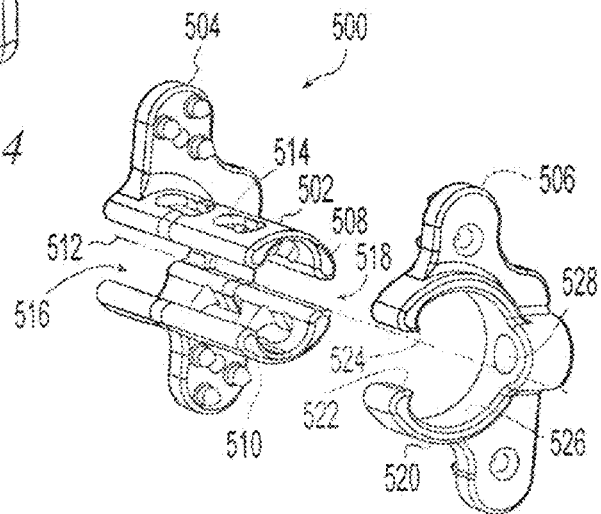


FIG. 15

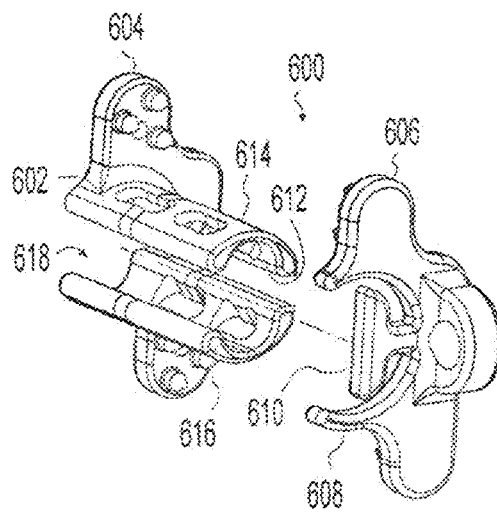


FIG. 16

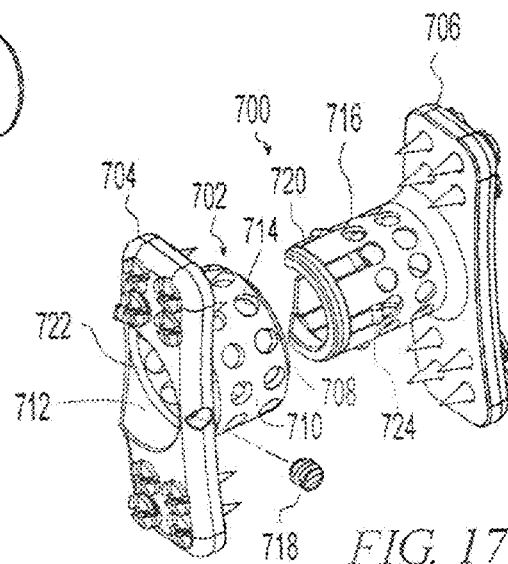
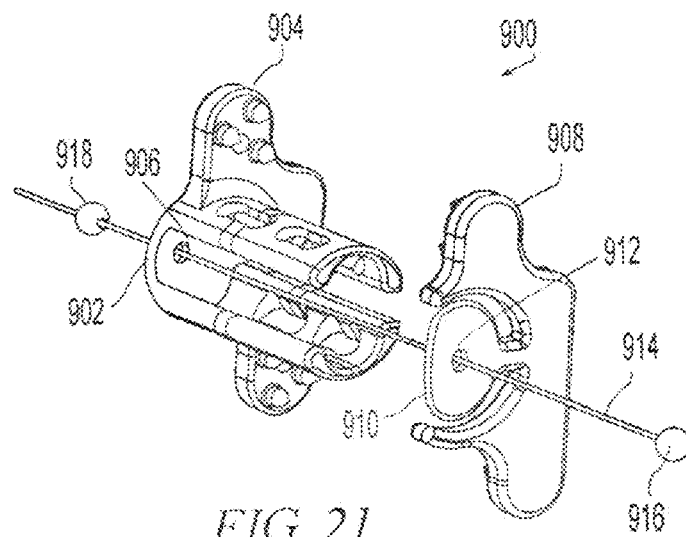
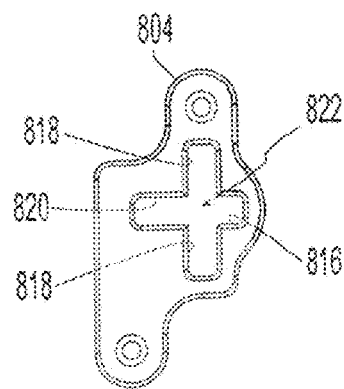
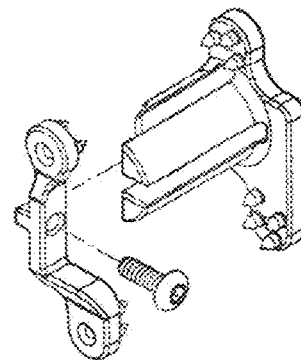
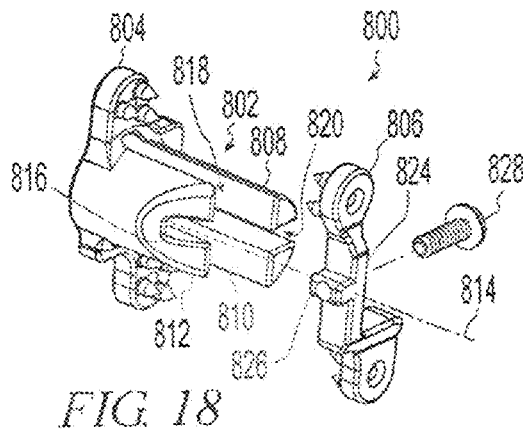


FIG. 17



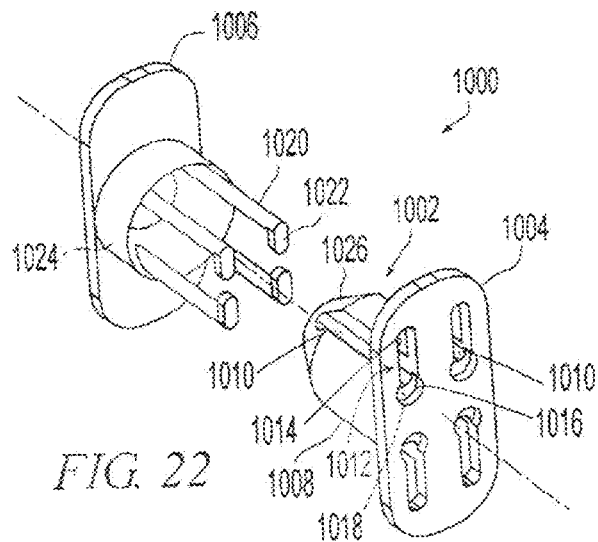


FIG. 22

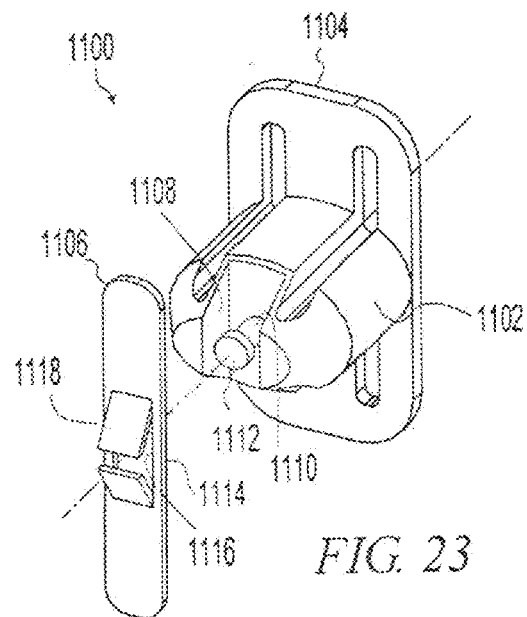


FIG. 23

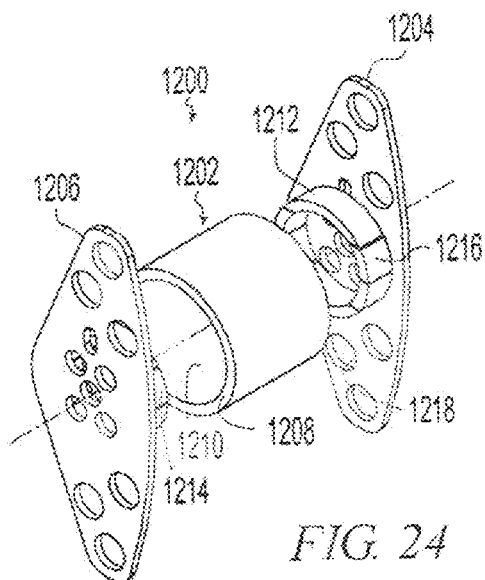
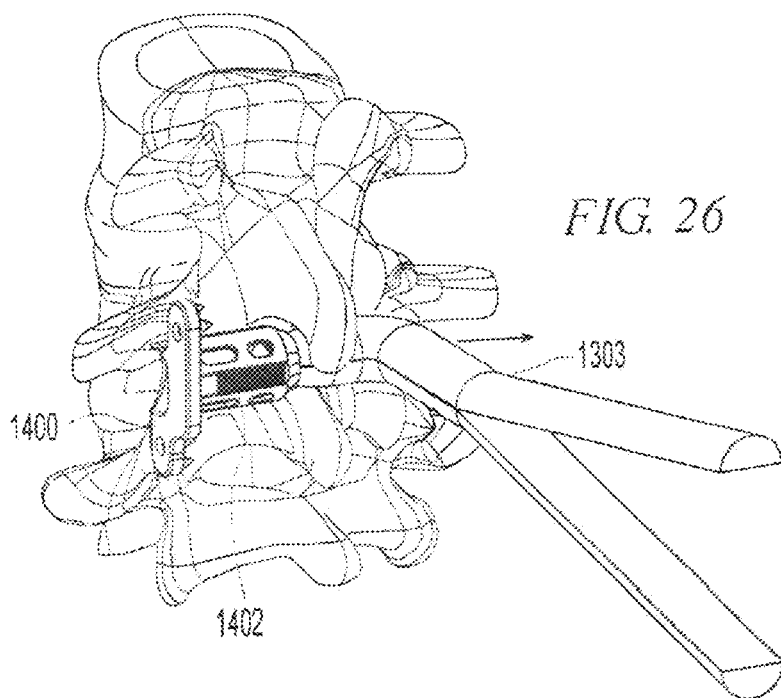
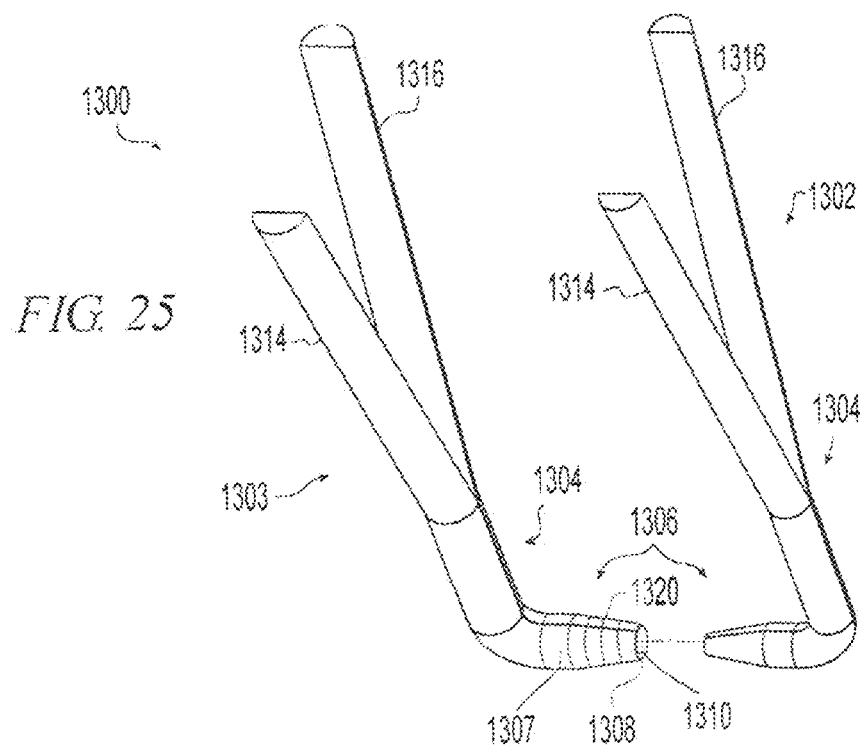


FIG. 24



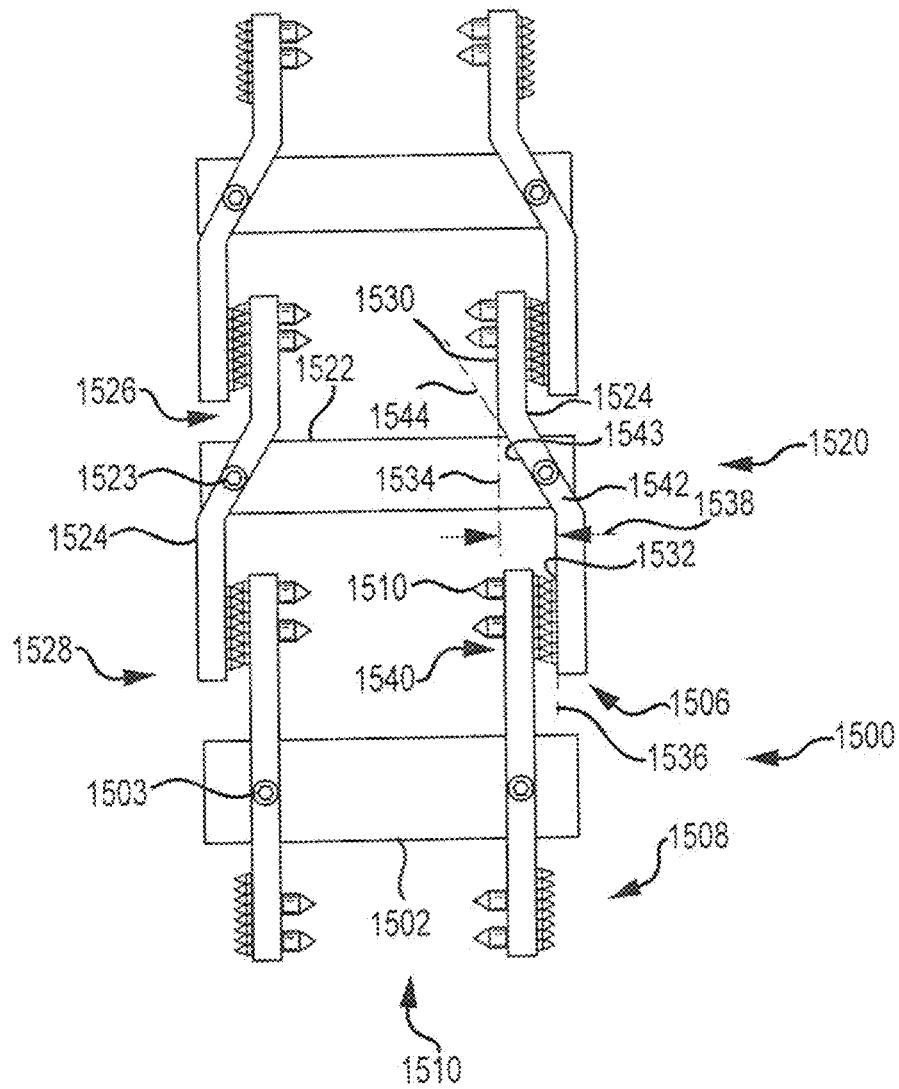


FIG. 27

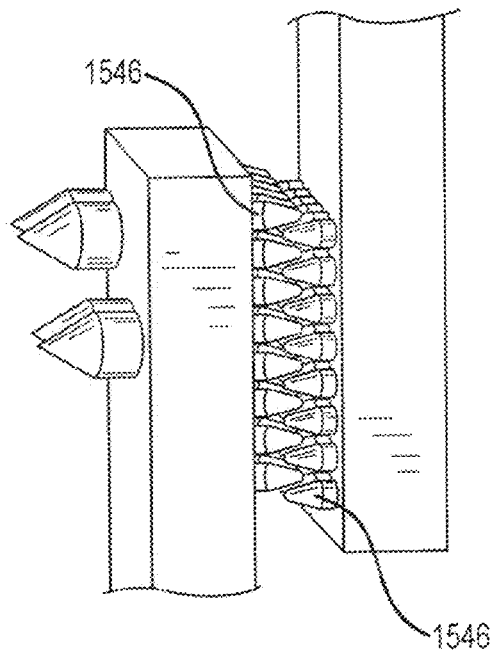


FIG. 28

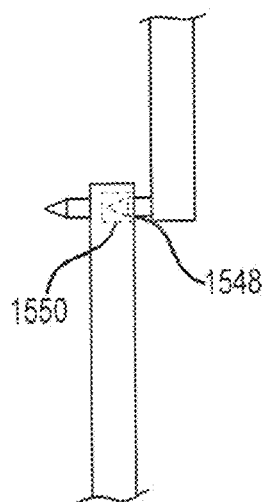


FIG. 29

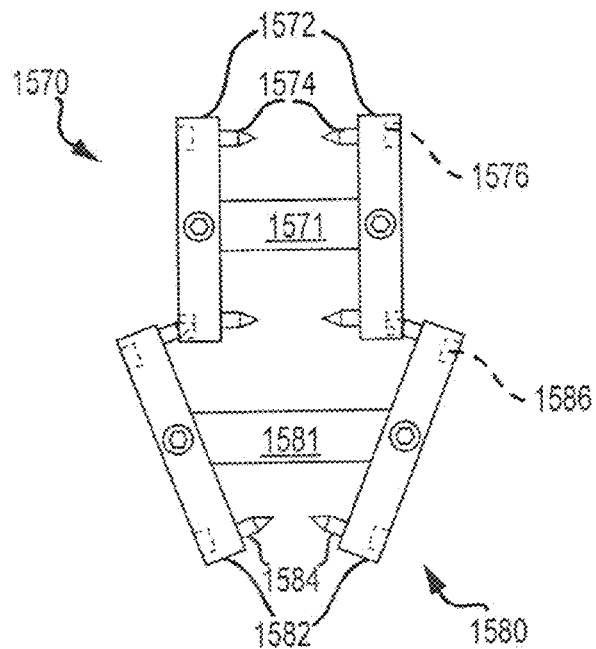


FIG. 30

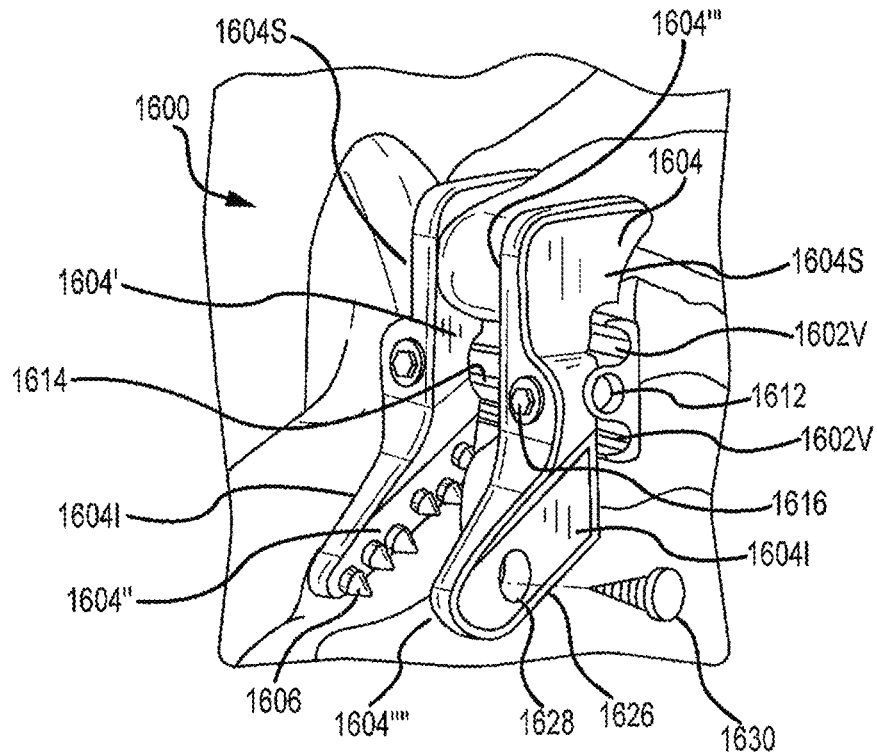


FIG. 31

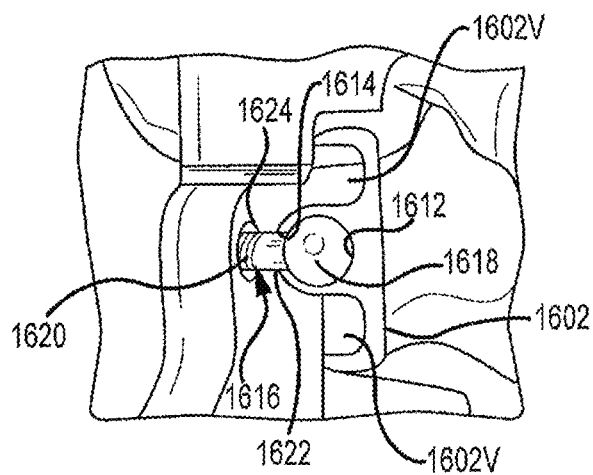


FIG. 32

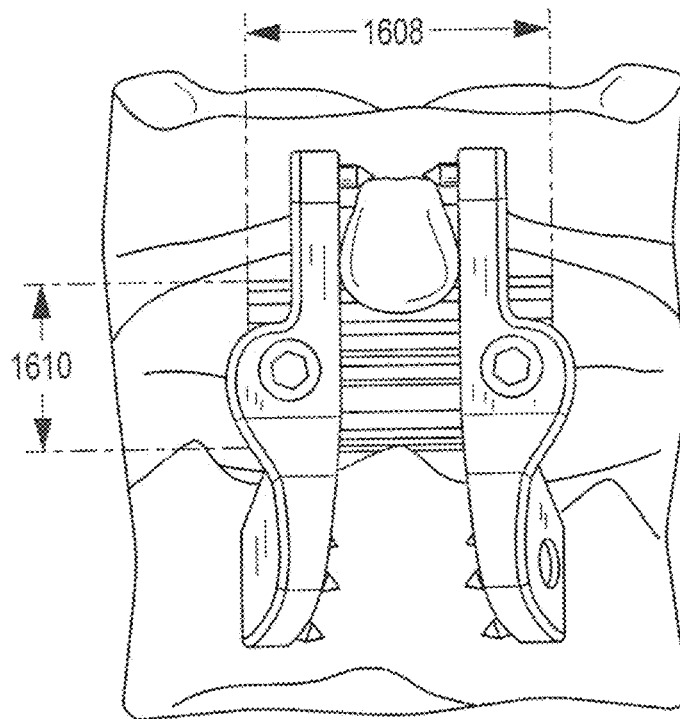


FIG. 33

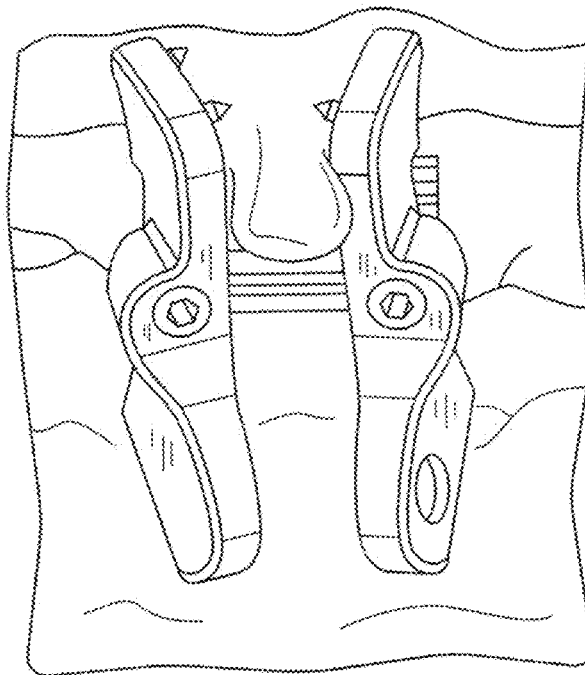


FIG. 34

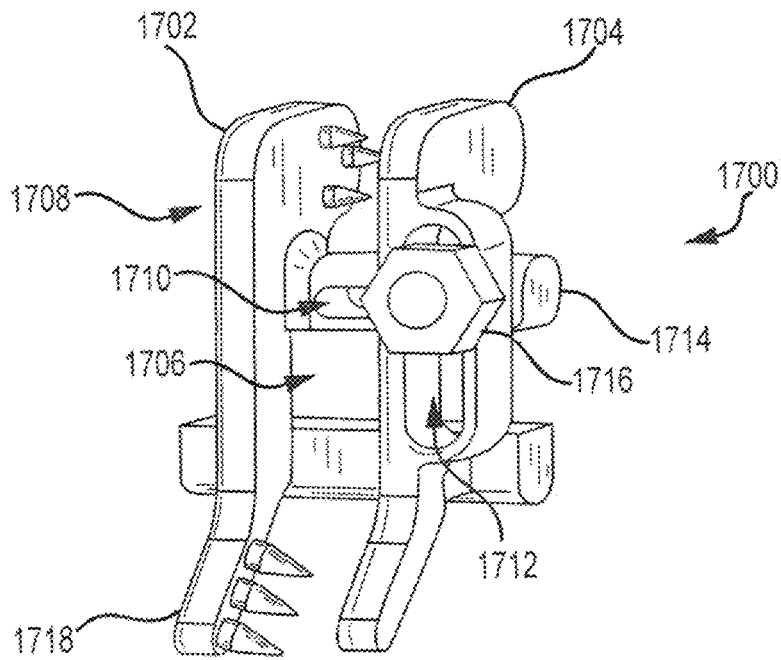


FIG. 35

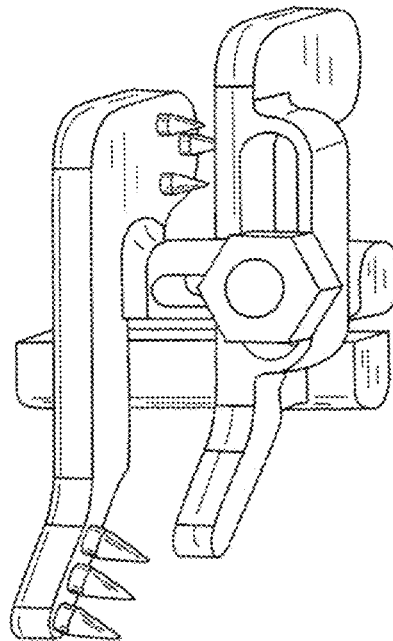


FIG. 36

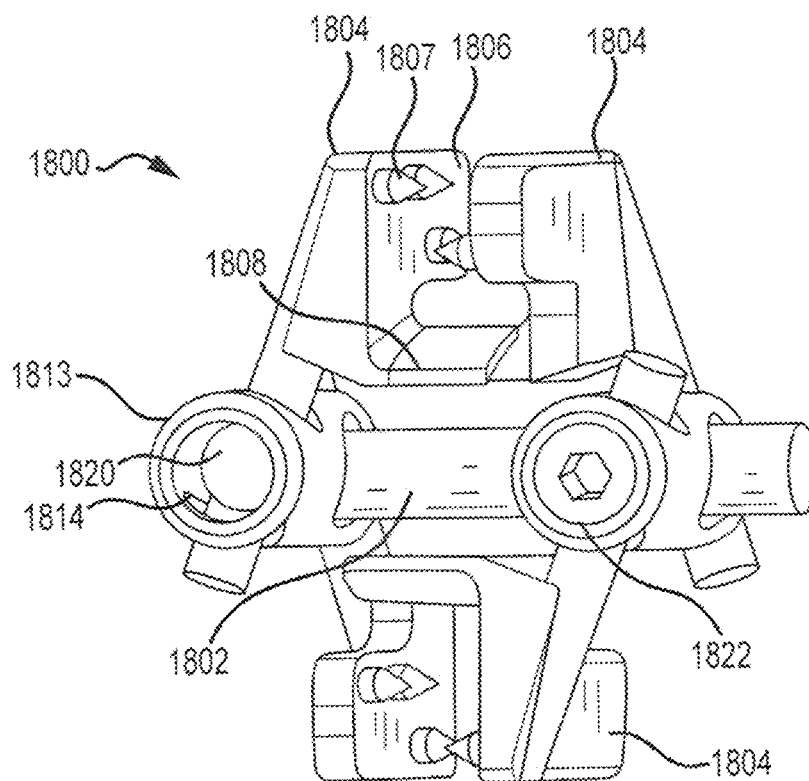


FIG. 37

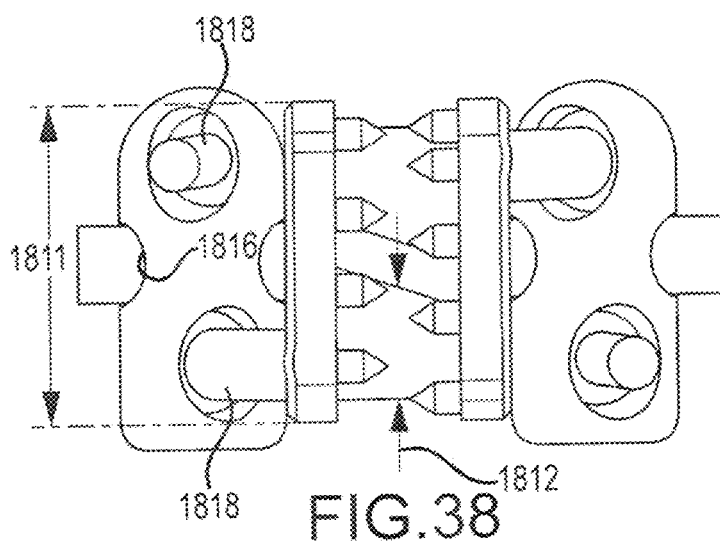


FIG. 38

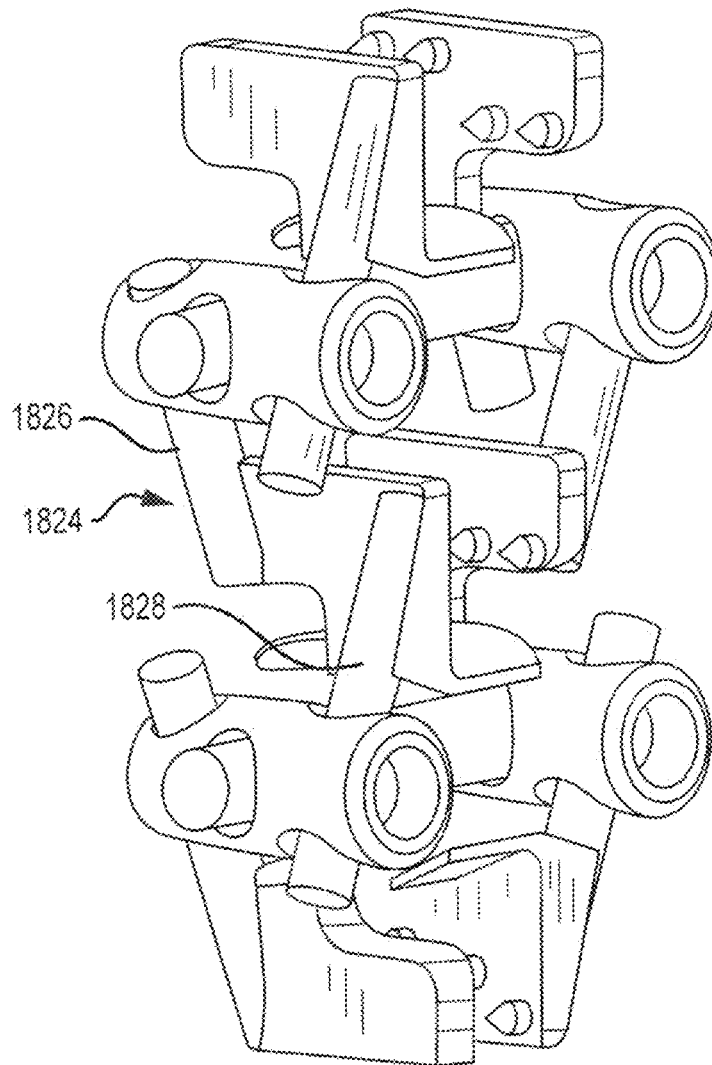


FIG. 39

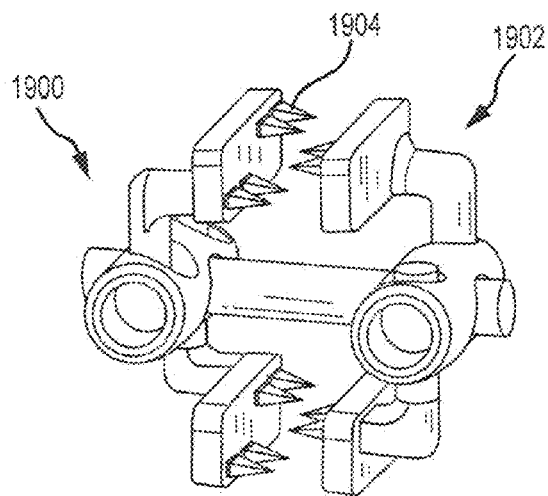


FIG. 40

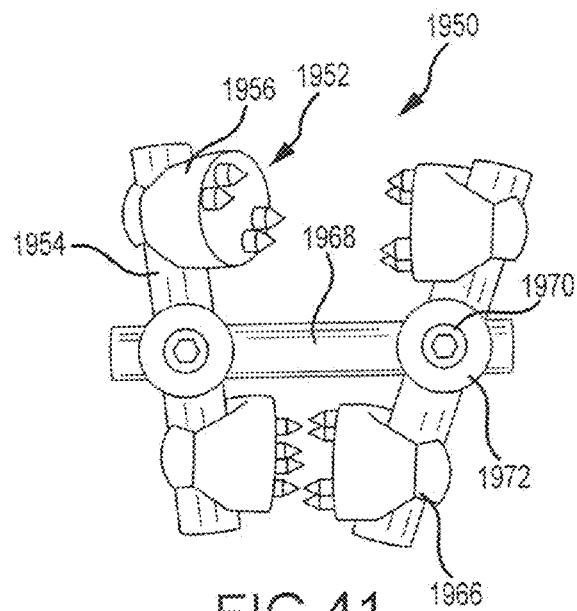


FIG. 41

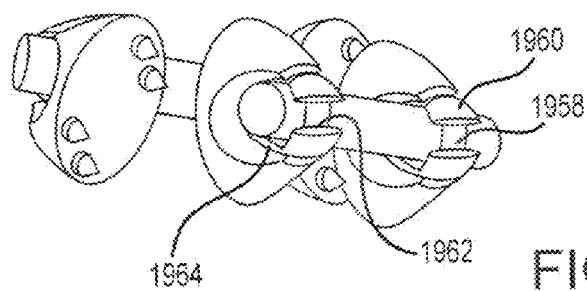


FIG. 42

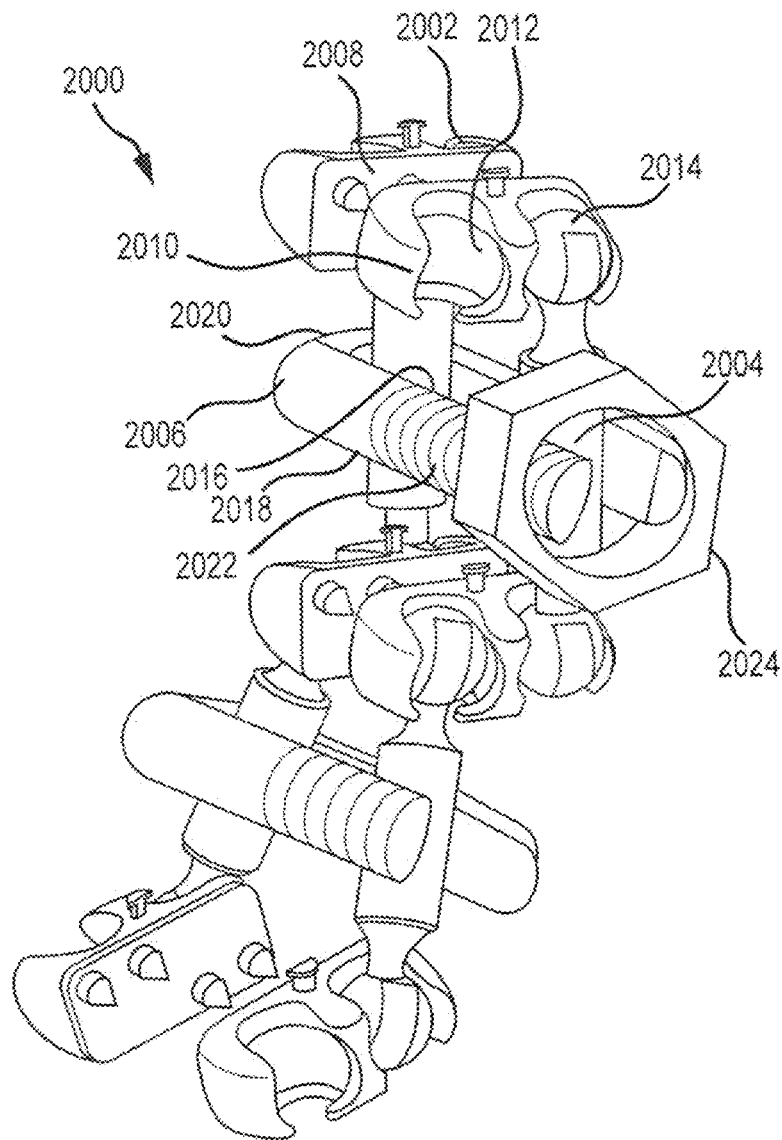


FIG. 43

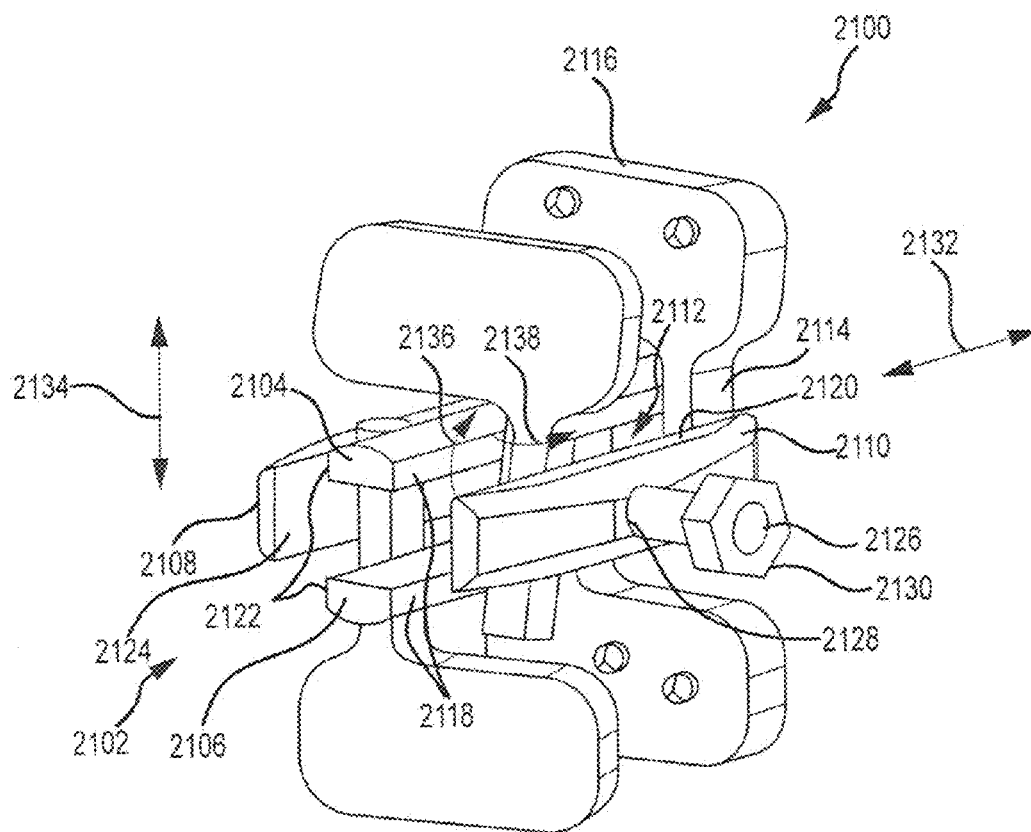


FIG.44

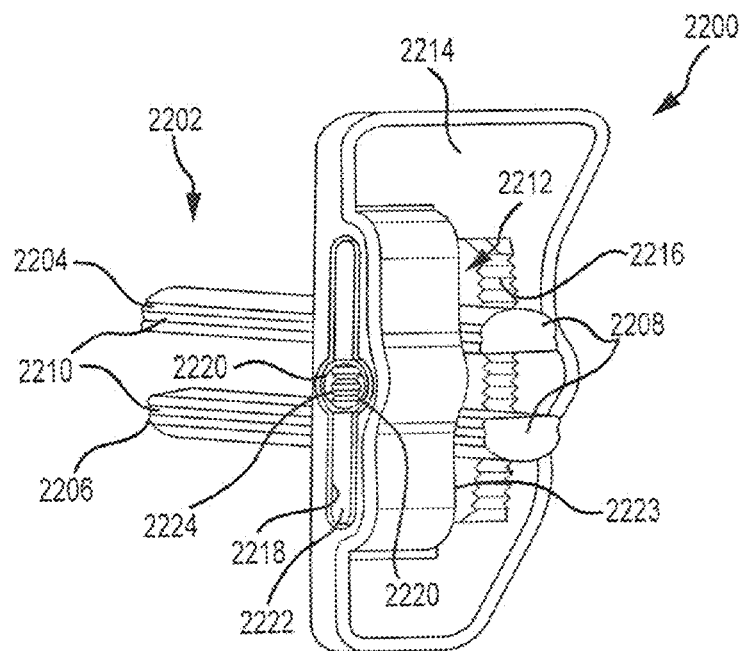


FIG. 45

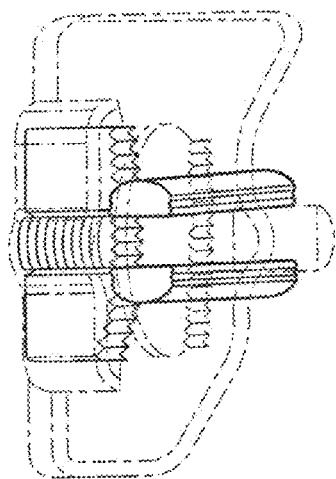


FIG. 46

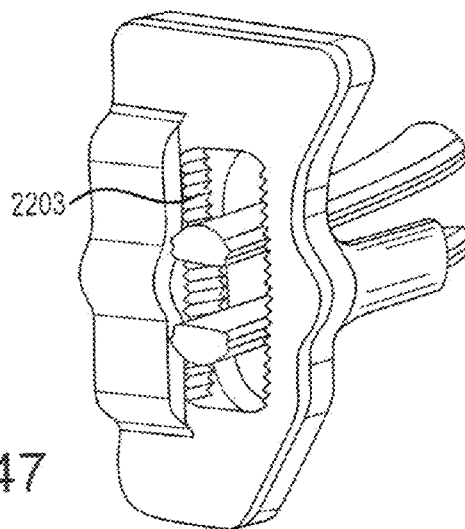
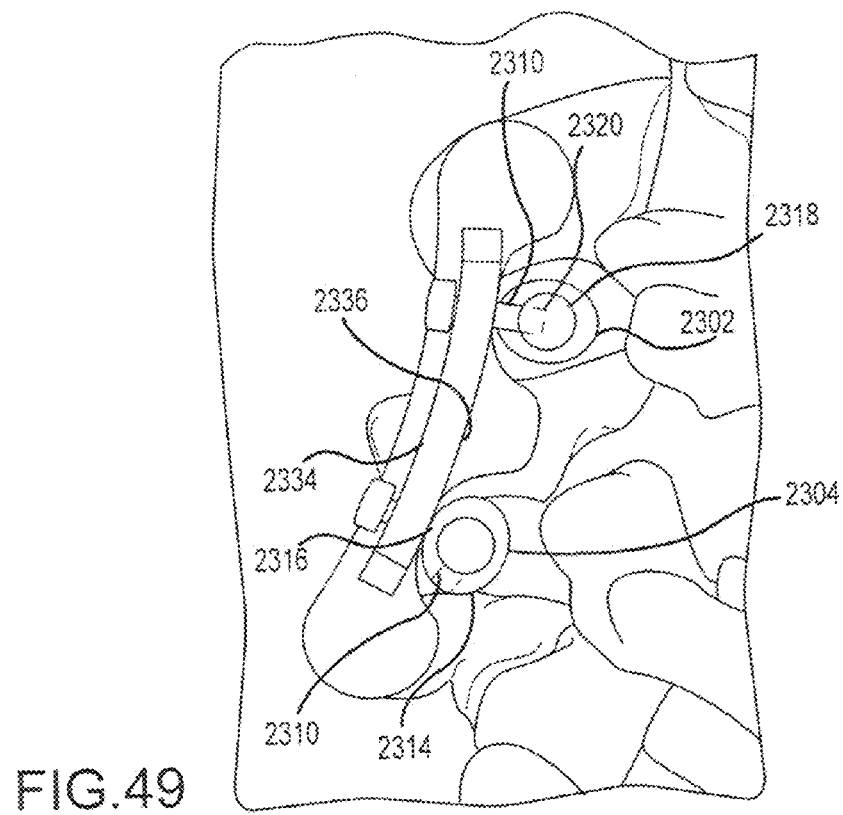
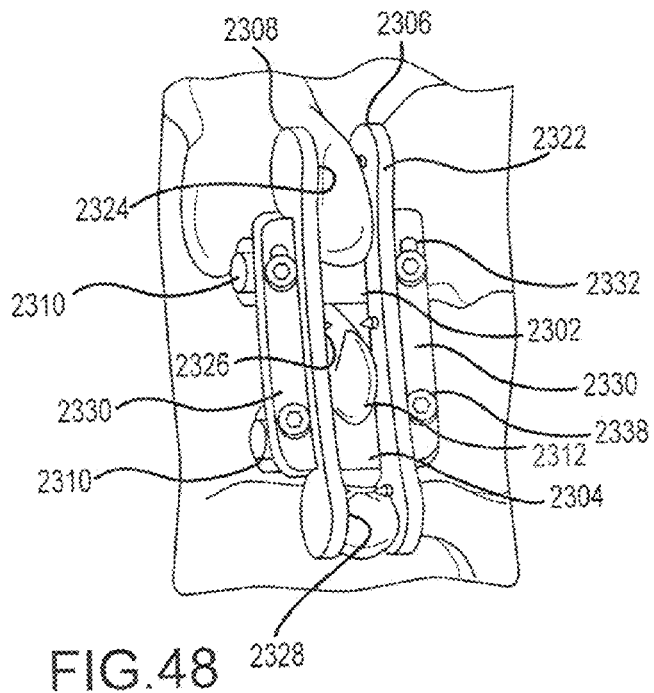


FIG. 47



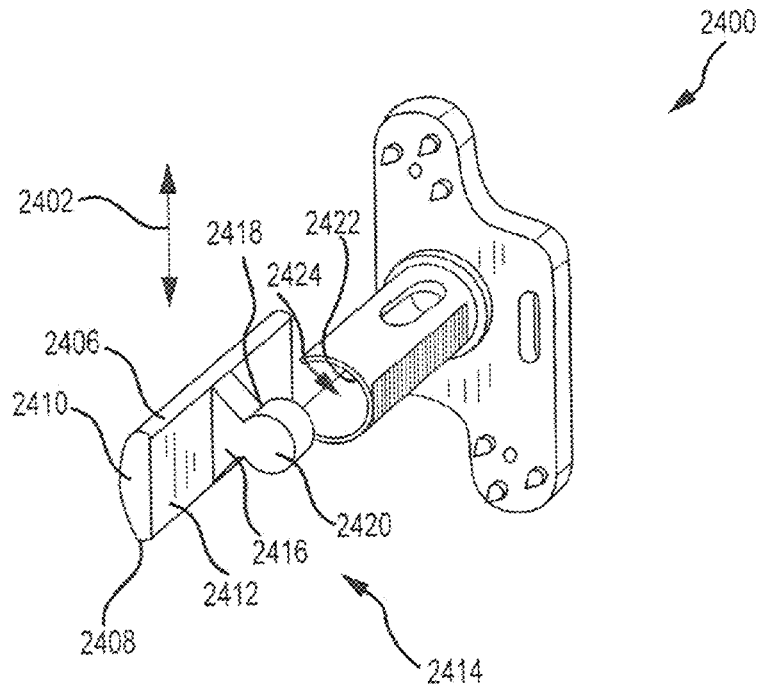


FIG. 50

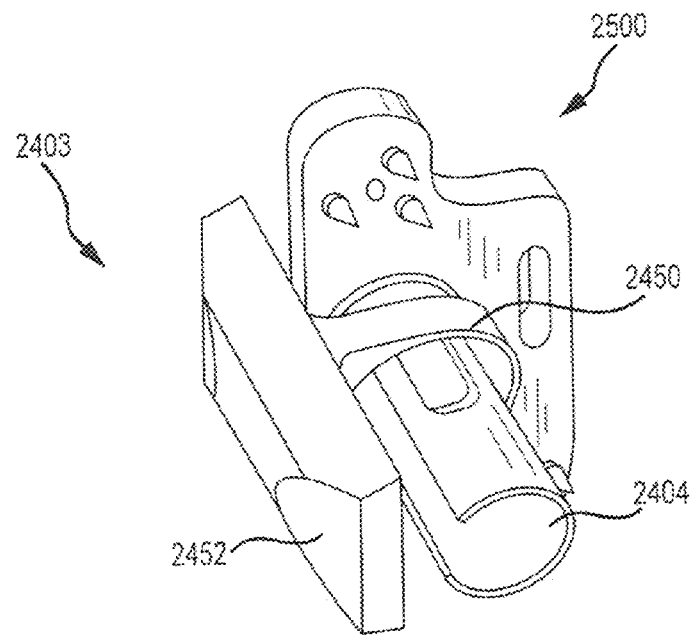
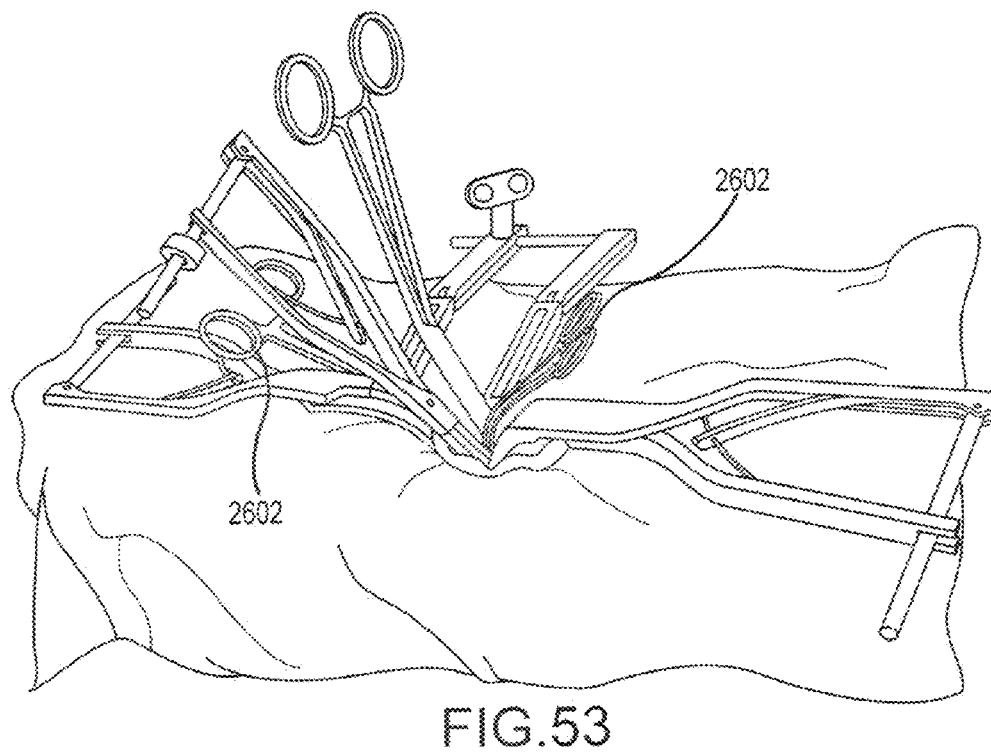
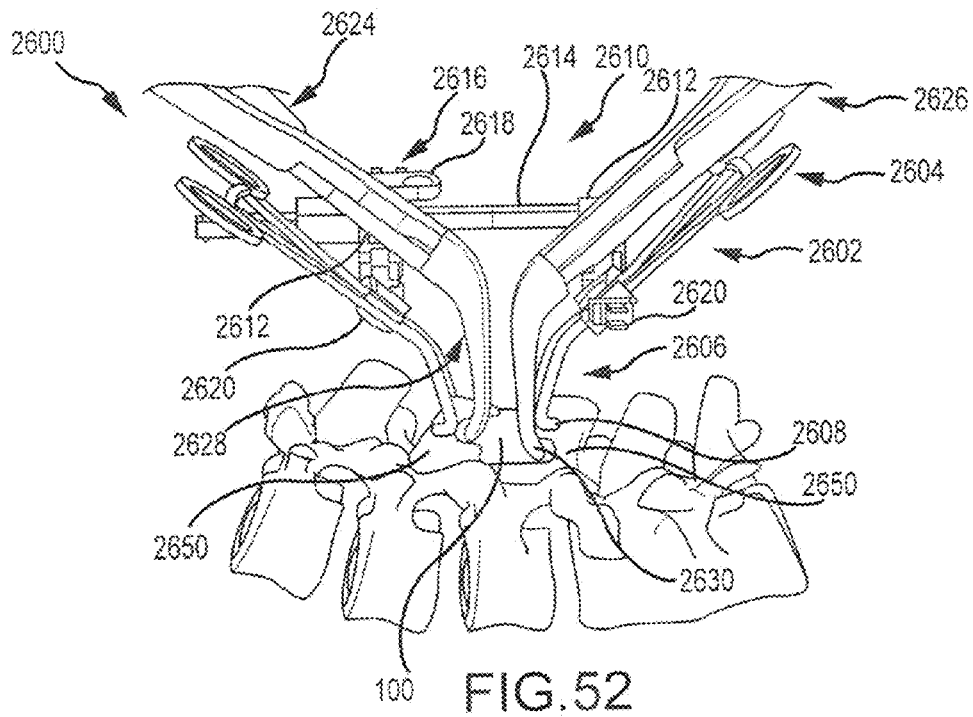


FIG. 51



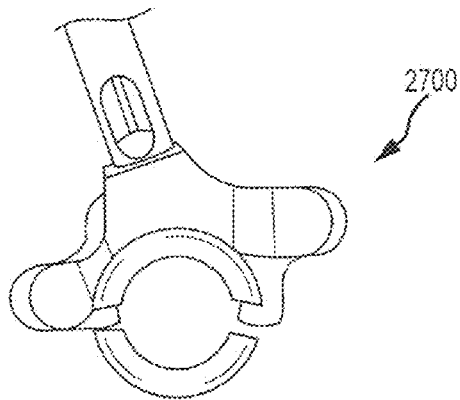


FIG. 54

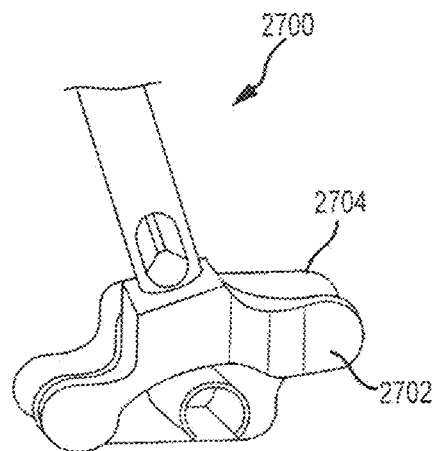


FIG. 55

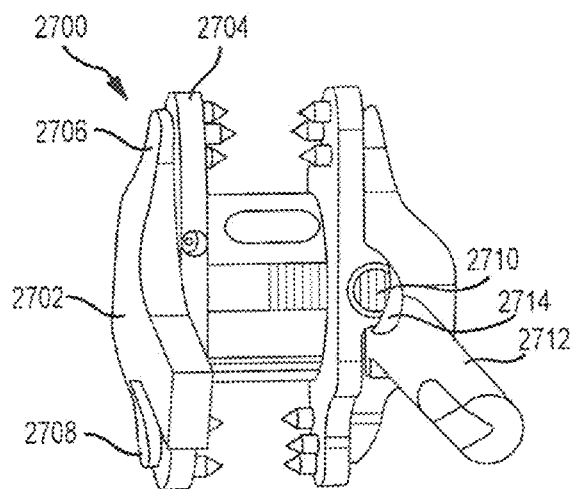
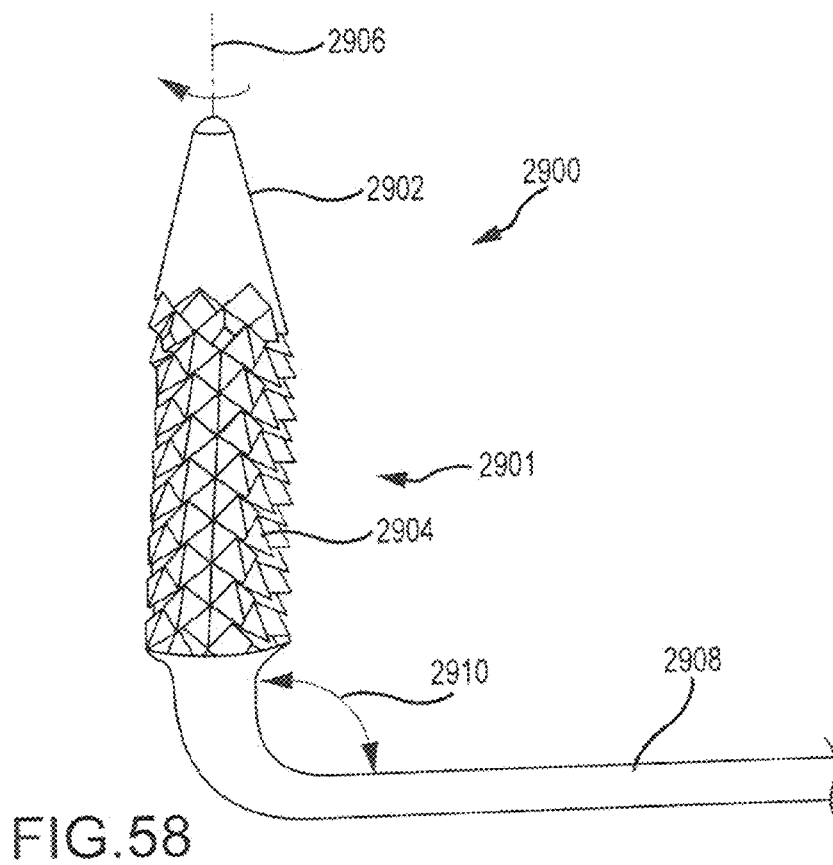
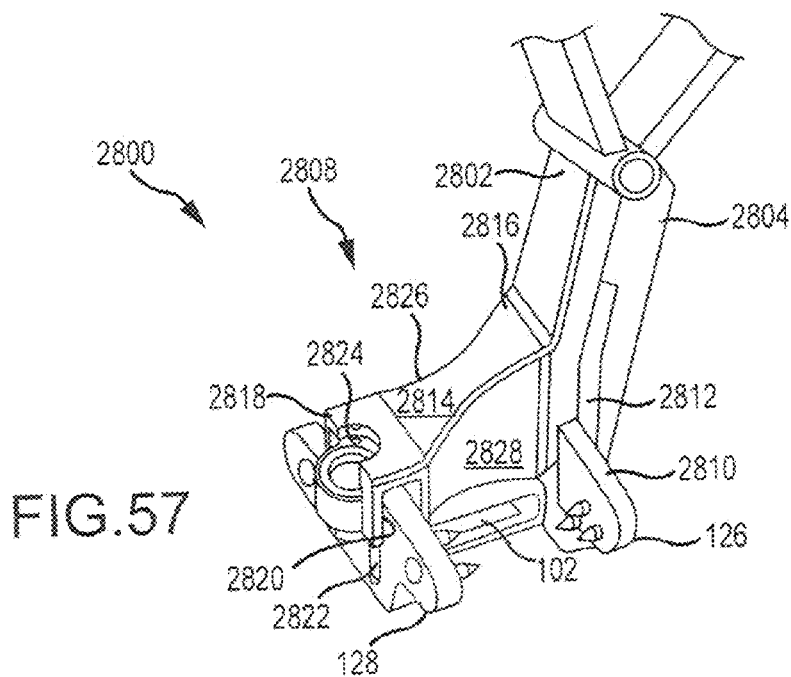


FIG. 56



1

SPINOUS PROCESS IMPLANTS AND ASSOCIATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 11/934,604, filed Nov. 2, 2007, which claims the benefit of U.S. Provisional Application No. 60/912,273, filed Apr. 17, 2007 and U.S. Provisional Application No. 60/884,581, filed Jan. 11, 2007, all of which are hereby incorporated by reference in their entirety. This application further claims the benefit of U.S. Provisional Application No. 61/165,354, filed Mar. 31, 2009, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to spinous process implants and associated methods.

BACKGROUND

The vertebrae of the human spine are arranged in a column with one vertebra on top of the next. An intervertebral disc lies between adjacent vertebrae to transmit force between the adjacent vertebrae and provide a cushion between them. The discs allow the spine to flex and twist. With age, spinal discs begin to break down, or degenerate resulting in the loss of fluid in the discs and consequently resulting in them becoming less flexible. Likewise, the disks become thinner allowing the vertebrae to move closer together. Degeneration may also result in tears or cracks in the outer layer, or annulus, of the disc. The disc may begin to bulge outwardly. In more severe cases, the inner material of the disc, or nucleus, may actually extrude out of the disc. In addition to degenerative changes in the disc, the spine may undergo changes due to trauma from automobile accidents, falls, heavy lifting, and other activities. Furthermore, in a process known as spinal stenosis, the spinal canal narrows due to excessive bone growth, thickening of tissue in the canal (such as ligament), or both, in all of these conditions, the spaces through which the spinal cord and the spinal nerve roots pass may become narrowed leading to pressure on the nerve tissue which can cause pain, numbness, weakness, or even paralysis in various parts of the body. Finally, the facet joints between adjacent vertebrae may degenerate and cause localized and/or radiating pain. All of the above conditions are collectively referred to herein as spine disease.

Conventionally, surgeons treat spine disease by attempting to restore the normal spacing between adjacent vertebrae. This may be sufficient to relieve pressure from affected nerve tissue. However, it is often necessary to also surgically remove disc material, bone, or other tissues that impinge on the nerve tissue and/or to debride the facet joints. Most often, the restoration of vertebral spacing is accomplished by inserting a rigid spacer made of bone, metal, or plastic into the disc space between the adjacent vertebrae and allowing the vertebrae to grow together, or fuse, into a single piece of bone. The vertebrae are typically stabilized during this fusion process with the use of bone plates and/or pedicle screws fastened to the adjacent vertebrae.

Although techniques for placing intervertebral spacers, plates, and pedicle screw fixation systems have become less invasive in recent years, they still require the placement of hardware deep within the surgical site adjacent to the spine.

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Recovery from such surgery can require several days of hospitalization and long, slow rehabilitation to normal activity levels.

More recently, investigators have promoted the use of motion preservation implants and techniques in which adjacent vertebrae are permitted to move relative to one another. One such implant that has met with only limited success is the artificial disc implant. These typically include either a flexible material or a two-piece articulating joint inserted in the disc space. Another such implant is the spinous process spacer which is inserted between the posteriorly extending spinous processes of adjacent vertebrae to act as an extension stop and to maintain a minimum spacing between the spinous processes when the spine is in extension. The spinous process spacer allows the adjacent spinous processes to move apart as the spine is flexed.

SUMMARY

The present invention provides a spinous process implant and associated methods.

In one aspect of the invention, an implant for placement between spinous processes of adjacent vertebrae includes a spacer and an extension. The spacer has a sidewall with superior and inferior surfaces operable to abut the spinous processes and maintain the spinous processes in spaced apart relationship. In one example, the sidewall extends generally parallel to a longitudinal axis. In other examples, the sidewall may converge, diverge, or define any other suitable shape relative to a longitudinal axis. The sidewall may be cylindrical, tapered, symmetrical, and/or asymmetrical relative to a longitudinal axis. The extension projects from the spacer transverse to the longitudinal axis to lie generally alongside the spinous processes of adjacent vertebrae and engage the spinous processes to limit the maximum spacing between the spinous processes.

In another aspect of the invention, the extension includes an adjustable fastener.

In another aspect of the invention, the extension includes a removable fastener.

In another aspect of the invention, an implant for placement between spinous processes of adjacent vertebrae includes a spacer having at least one transverse opening communicating from at least one of a superior and inferior outer surface inwardly to facilitate tissue in-growth.

In another aspect of the invention, the spacer includes a hollow interior and a plurality of transverse openings communicating from the superior and inferior outer surfaces to the hollow interior to facilitate tissue growth.

In another aspect of the invention, the spacer includes a porous structure and the transverse openings comprise a plurality of pores.

In another aspect of the invention, an implant for placement between spinous processes of adjacent vertebrae of a spine includes a spacer and separate extensions engageable with the spacer at its ends. The spacer is provided in a variety of lengths and superior to inferior surface spacings:

In another aspect of the invention, an implant for placement between spinous processes of adjacent vertebrae of a spine includes a spacer and a cerclage element. The cerclage element is offset posteriorly of the midline in use so that the spacer defines a fulcrum and the cerclage element is extendible around a portion of a vertebra and operative to impart a moment to the vertebra about the spacer.

In another aspect of the invention, instrumentation includes two instruments each having a working portion tapering from a larger cross-sectional dimension nearer a

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handle to a smaller cross-sectional dimension near the free end. The free end of one of the instruments defines a hollow tip sized to engage the free end of the first instrument and sized to engage the hollow tip of the implant.

In another aspect of the invention, a method includes inserting a spacer between spinous processes of adjacent vertebrae to provide both an extension stop and a flexion stop.

In another aspect of the invention, a method includes inserting a spacer between spinous processes of adjacent vertebrae and connecting a cerclage element to the adjacent vertebrae to impart a moment to the vertebrae about the spacer.

In another aspect of the invention, a method includes inserting a tapered instrument between adjacent spinous processes; engaging a tip of a spinous process spacer with the tip of the tapered instrument and passing the engaged pair back between the adjacent spinous process to insert the spacer between the spinous processes.

In another aspect of the invention, extensions may be provided that are shaped to allow extensions on adjacent implants to interleave.

In another aspect of the invention, extensions may be provided that permit an extension of one implant to overlie an extension of an adjacent implant.

In another aspect of the invention, an implant for placement between spinous processes may be shaped to accommodate a small or missing spinous process such as, e.g., on the sacrum of a patient.

In another aspect of the invention, an implant for placement between spinous processes may include a spacer that has a variable height.

In another aspect of the invention, an implant for placement between spinous processes may include a mechanism operable to distract adjacent spinous processes away from one another.

In another aspect of the invention, an implant for placement between spinous processes may include bone gripping extensions and a mechanism operable to simultaneously lock a desired horizontal spacing between extensions on opposing sides of a single spinous process and a desired vertical spacing between extensions engaged with adjacent spinous processes.

In another aspect of the invention, an implant for placement between spinous processes may include a spacers and/or extensions engageable with more than two spinous processes to constrain the motion of multiple spinal levels.

In another aspect of the invention, an implant for placement between spinous processes may include first and second spacers. The first and second spacers may be made of different materials.

BRIEF DESCRIPTION OF THE DRAWINGS

Various examples of the present invention will be discussed with reference to the appended drawings. These drawings depict only illustrative examples of the invention and are not to be considered limiting of its scope.

FIG. 1 is a cross sectional view of an implant according to the present invention in situ;

FIG. 2 is a side elevational view of the implant of FIG. 1 in situ;

FIG. 3 is an exploded perspective view of the implant of FIG. 1;

FIG. 4 is a front elevational view of the implant of FIG. 1;

FIG. 5 is a back elevational view of the implant of FIG. 1;

FIG. 6 is a top plan view of the implant of FIG. 1;

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FIG. 7 is a front elevational view of the implant of FIG. 1 showing the assembly in an alternate position;

FIG. 8 is a side elevational view of the implant of FIG. 1;

FIG. 9 is a perspective view of a pair of implants like that of FIG. 1 in situ;

FIG. 10 is a cross sectional view of an implant like that of FIG. 1 illustrating an alternate material and cerclage elements;

FIGS. 11-13 are side elevational views of an implant like that of FIG. 1 shown in use with cerclage elements;

FIGS. 14-24 are perspective views of alternative embodiments of the invention;

FIG. 25 is a perspective view of instrumentation for implanting the implant of FIG. 1;

FIG. 26 is a perspective view of the instrumentation of FIG. 25 in use to implant the implant of FIG. 1.

FIGS. 27-58 are perspective views of aspects of the invention.

DESCRIPTION OF THE ILLUSTRATIVE EXAMPLES

Embodiments of spinous process implants according to the present invention include a spacer and an extension extending outwardly from the spacer. The spinous process implant may be configured for insertion between adjacent spinous processes of the cervical, thoracic, and/or lumbar spine. The spacer may be provided in a variety of sizes to accommodate anatomical variation amongst patients and varying degrees of space correction. The spacer may include openings to facilitate tissue in-growth to anchor the spacer to the vertebral bodies such as tissue in-growth from the spinous processes. The spacer may be configured for tissue in-growth from superior and inferior spinous processes to cause fusion of the adjacent spinous processes. The openings may be relatively large and/or communicate to a hollow interior of the spacer. A hollow interior may be configured to receive bone growth promoting substances such as by packing the substances into the hollow interior. The openings may be relatively small and/or comprise pores or interconnecting pores over at least a portion of the spacer surface. The openings may be filled with bone growth promoting substances.

The spacer may have any suitable cross-sectional shape. For example, it may be cylindrical, D-shaped, C-shaped, H-shaped, include separated cantilevered beams, and/or any other suitable shape. The shape may include chamfers, fillets, flats, relief cuts, and/or other features to accommodate anatomical features such as for example the laminae and/or facets. The spacer may have a sidewall that is generally parallel, tapered, or irregularly shaped. The spacer may have a fixed height or it may have a variable height allowing for adjustment intraoperatively. A single spacer may be provided for a single level of spine correction or multiple spacers may be provided for a single level or multiple levels of spine correction. Where multiple spacers are provided, they may be made of the same or different materials.

The extension may extend transversely from the spacer relative to a spacer longitudinal axis to maintain the spacer between adjacent spinous processes. A single extension may extend in one or more directions or multiple extensions may be provided that extend in multiple directions. One or more extensions may be adjustable longitudinally relative to one another and/or the spacer to allow the extensions to be positioned relative to the spinous processes. A moveable extension may be provided that is movable axially relative to the spacer and another extension. Alternatively, a plurality of moveable extensions may be provided. For example, the

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extensions may clamp against the sides of the spinous processes to immobilize the spinous processes relative to one another and promote fusion between the adjacent vertebrae. The extensions may include fasteners engageable with the spinous processes. The fasteners may include sutures, wires, pins, straps, clamps, spikes, screws, teeth, adhesives, and/or other suitable fasteners. The fasteners may be integrated into the extensions or they may be modular. Modular fasteners may be adjustable, replaceable, and/or removable to allow tailoring of the kind and quality of fixation from rigid fixation to no fixation.

Extensions may be provided that permit an extension of one implant to overlie, or overlap, an extension of an adjacent implant. For example, the extensions may overlap similar to shingles overlapping. The extensions may be offset to further facilitate the overlapping of adjacent extensions. The extensions may have smooth surfaces that facilitate relative motion between overlapping portions of extensions. The extensions may have surfaces that engage one another to resist relative motion; for example, opposing surfaces of overlapping extensions may include pads, hooks, pins, teeth, bristles, surface roughness, adhesive, holes, loops, screws, bolts, and/or other features that permit one extension to grip another.

The implant may be shaped to accommodate a small or missing spinous process such as, for example, on the sacrum of a patient. For example, a portion of one or more extensions may flare outwardly to seat on a relatively broader and/or flatter portion of a bone such as the sacrum. Such an extension may include fasteners that are longer, sharper, and/or otherwise adapted to penetrate and grip the bone. The extensions may be angularly variable relative to one another to accommodate the shape of the underlying bone.

The spacer may have a fixed height or a variable height. A variable height spacer may include a first portion and a second portion having a variable height spacing that may be locked at a desired relative spacing. The height spacing may be adjustable and/or lockable simultaneously with or independently from a horizontal bone gripping spacing of the extensions. The height spacing may be adjustable by exerting a spacing force on a first and second portion with a removable instrument and then locking the desired spacing. The height spacing may be adjustable by operation of a mechanism incorporated into the implant itself. The height spacing may be adjustable and the desired spacing locked by a single mechanism. Height spacing adjustment of the spacer may be used to distract adjacent spinous processes away from one another.

The implant may include a mechanism for compressing and/or distracting extensions toward or away from one another while they are engaged with the bone of adjacent spinous processes such that the adjacent spinous processes are similarly compressed or distracted away from one another.

The implant may include spacers and/or extensions engageable with more than two spinous processes to treat multiple spinal levels.

The spacer, extensions, and/or fasteners may advantageously be made of different materials. For example, the spacer and extensions may be made of a relatively softer material while the fasteners may be made of a relative harder material. For example, the spacer and/or extension may be made of a polymer and/or other relatively soft material and the fastener may be made of a metal and/or other relatively hard material. The different materials may have different transmission properties such that one may appear well defined on a medical image and the other appear only dimly or not at all. For example, a metal portion of an implant will show plainly on an x-ray whereas a polymer portion will be

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much fainter. These properties can be used to allow a surgeon to see that certain portions, e.g. fasteners are engaged with bone while allowing a clear view through other portions to visualize the treatment site, e.g., the space between bones.

Cerclage may be used to stabilize the spinous process implant and/or to provide other benefits. For example, wires, straps, bands, cables, cords, and/or other elongated members may encircle the pedicles, laminae, spinous processes, transverse processes, and/or other spinal structures. The cerclage may be relatively inextensible to provide a hard check to spine flexion or the cerclage may be relatively extensible to provide increasing resistance to flexion. The cerclage may be relatively flexible and drapeable such as a woven fabric or it may be relatively rigid such as a metal band. The cerclage may have shape memory properties that cause it to resume a prior set shape after implantation. The cerclage may be independent of the spinous process implant or may engage it. For example, the cerclage may pass through a hollow interior of the spinous process implant and/or engage the extension. The cerclage may be offset from the spacer and provide a tensioning force that uses the spacer as a fulcrum to offload the disc and/or open the disc space.

The implant may be supplemented with bone growth promoting substances to facilitate fusion of adjacent vertebrae between spinous processes, laminae, transverse processes, facets, and/or other spinal structures. The bone growth promoting substances may be spaced from the implant, placed adjacent the implant, sandwiched between the implant and underlying bone placed inside the implant, coated onto the implant, and/or otherwise placed relative to the implant. If it is coated onto the implant it may cover the entire implant or only selected portions of the implant such as the extensions, fasteners, spinous process contacting portions of the spacer, and/or other portions.

In addition, bone growth promoting substances may include structural members that contribute directly to the support of the spacing between adjacent vertebrae. For example, a structural bone graft may be incorporated into, onto, around, and/or otherwise associated with the spacer and/or extensions to both provide structural support and a scaffold for new bone formation. For example, a structural piece of bone may engage with the spacer and extend beyond the spacer such that adjacent spinous processes rest on the structural bone.

As used herein, bone growth promoting substances may include bone paste, bone chips, bone strips, structural bone grafts, platelet derived growth factors, bone marrow aspirate, stem cells, bone growth proteins, bone growth peptides, bone attachment proteins, bone attachment peptides, hydroxylapatite, calcium phosphate, other ceramics, and/or other suitable bone growth promoting substances.

The implant and any associated cerclage or other components may be made of any suitable biocompatible material including among others metals, resorbable ceramics, non-resorbable ceramics, resorbable polymers, and non-resorbable polymers. Some specific examples include stainless steel, titanium and its alloys including nickel-titanium alloys, tantalum, hydroxylapatite, calcium phosphate, bone, zirconia, alumina, carbon, bioglass, polyesters, polylactic acid, polyglycolic acid, polyolefins, polyamides, polyimides, polyacrylates, polyketones, fluoropolymers, and/or other suitable biocompatible materials and combinations thereof.

The spinous process implant may be used to treat spine disease in a variety of surgical techniques including supraspinous ligament sacrificing posterior approaches, supraspinous ligament preserving posterior approaches, lateral approaches, and/or other suitable approaches. The spinous

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process implant may be used to treat spine disease by fusing adjacent vertebrae or by preserving motion between adjacent vertebrae. It may include only an extension stop such as a spacer, only a flexion stop such as flexible cerclage elements, or both a flexion and extension stop. The spinous process implant may be used to reduce loads on the facet joints, increase spinous process spacing, reduce loads on the disc, increase anterior disc spacing, and/or otherwise treat spine disease. Anterior effects may be accomplished by tensioning spine elements posterior to the spacer to apply a mechanical advantage to the spinal construct. Techniques for the spinal process implant may include leaving the tissues at the surgical site unmodified or modifying tissues such as trimming, rasping, roughening, and/or otherwise modifying tissues at the implant site.

FIGS. 1 and 2 depict posterior and lateral views of a pair of adjacent vertebrae of the lumbar spine 10. A superior vertebra 12 is separated from an inferior vertebra 14 by a disc 16. Each vertebra includes a pair of transverse processes 18, 19, a posteriorly projecting spinous process 20, 21, and a pair of laminae 22, 23 connecting the transverse processes 18, 19 to the spinous process 20, 21. In addition to the connection through the disc 16, the vertebrae 12, 14 articulate at a pair of facet joints 24.

FIGS. 1-9 illustrate an exemplary spinous process implant 100. The implant 100 includes a spacer 102 positioned between the spinous processes 20, 21. The height 104 of spacer 102 limits how closely the spinous processes 20, 21 can move together. Thus, the spacer 102 maintains a minimum distance between the spinous processes 20, 21. In the case of spine disease involving posterior subsidence of the adjacent vertebra, insertion of the spacer 102 between the spinous processes 20, 21 will move the vertebrae apart and relieve pressure on nerve tissue and the facet joints 24.

As shown in FIG. 3, the spacer 102 includes a first end 106, a second end 108, and a longitudinal axis 110 extending from the first end to the second end. In the illustrated example, the spacer 102 has a sidewall 112, generally parallel to the longitudinal axis 110, including superior and inferior outer surfaces 114, 116. Transverse openings 118 (see also FIG. 6) communicate from the superior and inferior outer surfaces 114, 116 inwardly to facilitate tissue in-growth. The exemplary spacer 102 includes a hollow interior 120 bounded by an inner surface 122 such that the openings 118 communicate from the outer surface to the hollow interior 120. Bone growth promoting substances 124 are shown packed into the hollow interior 120 in FIGS. 1 and 2 to promote fusion of the vertebrae 12, 14 by bone growth between the spinous processes 20.

The spinous process implant 100 further includes a first extension 126 projecting outwardly from the spacer 102 transverse to the longitudinal axis 110 to lie generally alongside the superior spinous process. Abutment of the first extension 126 with the spinous process 20 helps to maintain the spacer 102 between the spinous processes 20. In the exemplary spinous process implant 100, the first extension 126 is fixed relative to the spacer 102 and the implant includes a second extension 128 mountable to the spacer for axial movement relative to the first extension 126. The second extension 128 may be moved toward the first extension 126 to approximate the width of the spinous process 20 and better stabilize the implant 100. It is fixed in place by tightening a set screw 130 against the spacer 102. The extensions 126, 128 include fasteners 132, 134, 136 projecting from the extensions 126, 128 to engage the spinous process 20 to fix the spacer 102 to the spinous process 20. FIG. 1 depicts additional bone growth promoting substance in the form of a strips of bone 125 sandwiched between the extensions 126, 128 along the sides

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of the spinous processes 20 to promote bone growth along the sides of the spinous processes to further enhance fusion of the vertebrae 12, 14. The extensions 126, 128 preferably extend inferiorly (as shown) as well as superiorly to optionally attach to the inferior spinous processes to immobilize the spinous processes 20 relative to one another while fusion takes place.

The fasteners 132, 134, and 136 may take any suitable form. They may be made integral with the extensions 126, 128 such as by machining or casting them with the extensions or they may be formed separately and permanently attached to the extensions 126, 128. Fastener 132 is a sharpened spike that threadably engages the extension 126. The threaded engagement allows the fastener 132 to be replaced with a different fastener 132. For example, the fastener 132 may be replaced by one that has a different shape, a different size, a different material, or a different surface coating. The threaded engagement also allows the fastener 132 to be adjusted to extend by varying amounts from the extension 126 to vary how it engages the bone. Thus, the fastener 132 can be adjusted to fit differently shaped bones or to penetrate into a bone by varying amounts. For example, multiple threaded fasteners 132 can be adjusted to extend by different amounts to conform to curved or angled bone. Finally, the threaded engagement allows the user to remove the fastener 132 when fixation is not desired such as when it is desired to use implant 100 in a non-fusion procedure as an extension stop without limiting flexion.

Fasteners 134 and 136 are provided as multi-spike pods allowing a plurality of spikes to be quickly adjusted, changed, or omitted. Fastener 134 includes a non-circular tab 138 engageable with a non-circular opening 140 in the extension 126. The non-circular engagement prevents the fastener 134 from rotating. The tab 138 may form a press-fit, snap-fit, or other suitable engagement with the opening 140. The tab 138 may be further secured by a supplemental screw 142. Fastener 136 includes a threaded shaft 144 threadably engaged with a base member 146 to allow the length of the fastener 136 to be adjusted. The shaft 144 engages the extension 126 in rotating and pivoting manner such that the fastener 136 can be adjusted rotationally and angularly to engage the bone surface. In the illustrative embodiment, the shaft 144 terminates in a spherical ball 148 that engages the opening 140 in a ball-and-socket arrangement for three degrees of freedom. However, any mechanism that allows any number of degrees of freedom may be used. The fastener 136 may be allowed to move in use so that as the extension 126 is pressed toward a bone the fastener 136 adjusts to the angle of the bone surface. The fastener 136 may also be secured such as by screw 142 to adjust the tension in the joint and/or to lock the fastener 136 in a predetermined orientation.

FIG. 4 illustrates the axial relationship of fasteners on the opposing extensions 126, 128. In the illustrative implant 100, the fasteners 132 at the top of the implant 100 are shown aligned along a common axis 150. The fasteners 134 at the bottom of the implant 100 are shown offset so that they can interleave if necessary as they are pressed into a bone. Any combination of fastener type, number, and alignment may be provided on the implant 100.

As seen in FIGS. 5 and 6, the ends 106, 108 of the spacer 102 include anterior chamfers 152. These chamfers 152 allow the ends 106, 108 to clear posteriorly facing structures of the vertebrae 12, 14 such as the facet joints 24. Also, as seen in FIGS. 5 and 6, the spacer 102 is offset anteriorly relative to the extensions 126, 128 such that the longitudinal axis 110 of the spacer 102 is anterior of the midline 154 of the extensions 126, 128. The anterior offset of the spacer 102 allows it to fit

deeply between the spinous processes **20, 21** while the extensions **126, 128** fit alongside the spinous processes **20, 21**.

As best seen in FIGS. **3** and **8**, the second extension **128** defines an aperture **155** conforming generally to the cross-sectional shape of the spacer **102**. In the illustrative embodiment of FIGS. **1-9**, the aperture **155** opens anteriorly to form a “C”-shape. Tabs **156** extend inwardly from the superior and inferior portions of the aperture to slidably engage elongated slots **158** in the superior and inferior surfaces of the spacer **102**. The second extension **128** can be translated longitudinally toward and away from the first extension **126**. Tightening the set screw **130** against the posterior side **160** of the spacer **102** forces the tabs **156** posteriorly against the sides of the slots **158** and locks the second extension **128** in place longitudinally. The posterior side **160** of the spacer **102** may be roughened as shown to better grip the set screw **130**. The set screw **130** may also dig into the surface of the spacer **102** upon tightening to positively grip the spacer **102**. The aperture **155** may conform closely to the spacer **102** to constrain the second extension **128** to generally parallel motion relative to the first extension **126**. Alternatively, the aperture **155** may be larger than the spacer **102** by a predetermined amount to permit a predetermined amount of angular adjustment of the second extension **128** relative to the first extension **126** as shown in FIG. **7** to allow the extension **128** to adjust to the underlying bone surface.

As best seen in FIG. **8**, the second extension **128** includes a first lobe **161** having a first lobe centerline **162** and a second lobe **164** having a second lobe centerline **166**. In the illustrative embodiment, the first lobe centerline **162** and the second lobe centerline **166** are parallel and spaced apart so that the second extension **128** has a generally “Z”-shaped plan form. This shape allows the extension of one implant **100** to interleave, if necessary, with another implant **100** in a multilevel surgery as shown in FIG. **9** to permit close spacing of the implants, and/or longer extension lobes for more extensive bone engagement. In the illustrative embodiment of FIGS. **1-9**, the centerlines **162** and **166** are offset equidistantly from the midline **154** of the second extension **128**. The centerlines **162** and **166** may vary from parallel and they may be offset asymmetrically to form different shapes to accommodate different vertebral anatomy. For example, the shape may be tailored for different portions of the spine **10**. In the illustrative embodiment of FIGS. **1-9**, the first extension **126** has the same shape as the second extension **128**. However, the shape may be varied between the first and second extensions **126, 128**.

FIG. **10** depicts an implant **200** having a spacer **202** and first and second extensions **204, 206**. The spacer **202** includes pores **208** for tissue to grow into. The pores **208** may be individual openings spaced from one another, interconnecting openings, or combinations of individual and interconnecting openings. The spacer **202** may be a monolithic block having uniform porosity throughout. Alternatively, the spacer **202** may include an outer porous layer **210** and an inner layer **212** of different composition. For example, the inner layer **212** may be solid, porous, hollow, or some other configuration. A porous inner layer may have pores of a different size and/or distribution than the outer layer **210**. Similarly, any porous portion may have uniform porosity or porosity that varies in pore size or density. A variety of pore configurations are suitable. Preferably the pore size is in the range of $1\text{ }\mu\text{m}$ to 2 mm . More preferably, the pore size is in the range of $1\text{ }\mu\text{m}$ to $500\text{ }\mu\text{m}$. Still more preferably, the pore size is in the range of $75\text{ }\mu\text{m}$ to $300\text{ }\mu\text{m}$. The pores may be produced by a variety of processes such as sintering of particles; leaching a soluble component from the material; matting, weaving, or otherwise

combining fibers: and/or by any other known process. The pore size may be tailored to preferentially promote hard tissue growth, soft tissue growth, or a combination of hard and soft tissue growth. The extensions **204, 206** may be solid or they may have large and/or small openings to encourage bone growth in and/or around the extensions **204, 206**. The spacer **202** and/or extensions **204, 206** may also be coated as previously described.

The extensions **204, 206** may be fixed and/or adjustable. In the illustrative implant **200** of FIG. **10**, the first extension **204** is fixed to one end of the spacer **202** and the second extension **206** is translatable along the spacer **202** to allow the extensions to be placed adjacent the spinous processes. The extensions **204, 206** are shown with optional spikes **214** that may engage the spinous processes **20, 21** to fix the spinous processes **20, 21** relative to one another.

FIG. **10** also depicts the use of cerclage in conjunction with the implant **200**. For example, one or more flexible bands **216** are placed around the lamina **22, 23** to provide a flexion stop. The band **216** may help carry the load exerted on the spikes **214** during spine flexion. Alternatively or in addition to the band **216**, one or more bands **218, 220** may be placed around the transverse processes **18, 19**.

FIGS. **11-13** depict additional examples of the use of cerclage in conjunction with a spinous process implant **300** according to the present invention. The implant includes a spacer **302** for placement between adjacent spinous processes **20, 21** and an extension **304**. In the example of FIG. **11**, a band **310** of flexible material is looped around the spinous processes **20, 21**. By placing the band **310** behind the areas **312, 314** where the spinous processes contact the spacer **302** an offset **318** is created. Tightening of the band **310** creates a moment **320, 322** on each vertebra **12, 14** that offloads some of the pressure on the disc **16** between the adjacent vertebrae **12, 14**. With increased tightening of the band **310**, the anterior spacing **324** of the vertebrae **12, 14** may actually be increased. Thus, by using the spinous process implant **300** in combination with the band **310**, the vertebrae **12, 14** may be levered apart with the implant **300** being used as the fulcrum. In addition to the advantages already mentioned, this combination produces an anterior disc space effect with a posterior spinous process procedure that is less invasive than typical disc spacing procedures.

In the examples of FIGS. **12** and **13**, the implant **300** includes a mechanism for attaching the cerclage band **310** to the implant **300**. In the example of FIG. **12**, the mechanism includes openings **330, 332** in the superior and inferior ends of the extension **304**. By attaching the band **310** to the extension **304**, the band **310** and extension **304** help stabilize one another against anterior-posterior displacement. This attachment also helps position the band **310** at a predetermined offset **318** from the spacer **302**. In the example of FIG. **13**, the band **310** is looped through a hollow interior of the spacer **302** itself. In this example, the band is not offset and produces minimal or no moment on the vertebrae.

FIGS. **14-24** illustrate alternative mechanisms for attaching a movable extension to the implant of FIG. **1**. Referring to FIG. **14**, an implant **400** includes a spacer **402**, a first extension **404** and a second, movable extension **406**. The movable extension **406** includes a body in the form of a ring **408** with an inner surface **410** generally conforming to the outer surface of the spacer **402** so that the ring is slidably receivable on the spacer **402**. A set screw **412** is tightened against the spacer **402** to fix the movable extension **406** at a desired position on the spacer **402**. Tightening of the set screw **412** biases the movable extension **406** posteriorly relative to the spacer **402**. The anterior portion **414** of the ring presses

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against the anterior portion **416** of the spacer **402** to counter this posterior bias and allow the set screw **412** to lock the extension **406**. The spacer **402** may include a plurality of indentations **418** to create a positive engagement with the set screw **412** at predetermined axial locations. The ring **408** may be sized to permit a predetermined amount of tilting of the extension **406** relative to the spacer **402**.

Referring to FIG. 15, an implant **500** includes a spacer **502**, a first extension **504**, and a second, movable extension **506**. The spacer **502** includes a plurality of cantilevered beams **508**, **510** projecting parallel to a longitudinal axis **512** away from the first extension **504**. In the example of FIG. 15, the spacer **502** includes a pair of opposed "C"-shaped beams **508**, **510** with their concave surfaces directed inwardly. The spacer **502** includes openings **514** through the beams **508**, **510** and defines elongated openings **516**, **518** anteriorly and posteriorly between the beams. The movable extension **506** includes a body in the form of an interrupted ring **520**. The ring **520** is open anteriorly and the margins of the opening define posteriorly directed hooks **522**, **524**. The inner surface **526** of the ring conforms generally to the outer surface of the beams **508**, **510** so that the ring is slidably receivable on the spacer **502**. The open anterior configuration of the ring **520** provides clearance to ease sliding of the ring in-vivo. A set screw **528** is tightened against the spacer **502** to fix the movable extension **506** at a desired longitudinal position on the spacer. The hooks **522**, **524** curve around a portion of the anterior edge of the beams **508**, **510** to resist posterior translation of the ring relative to the spacer **502** when the set screw **528** is tightened.

Referring to FIG. 16, an implant **600** is depicted that is similar to implant **500** of FIG. 15 having a spacer **602**, first extension **604**, and movable extension **606**. However, the ring **608** is truncated anteriorly to provide even more anterior clearance than the ring **520** of FIG. 15. The ring **608** includes a key **610** projecting anteriorly from the posterior side of the ring **608** and expanding superiorly and inferiorly to engage the inner surface **612** of the beams **614**, **616** to resist posterior translation of the ring relative to the spacer **602**. The key **610** also partially blocks the hollow interior **618** of the spacer **602** to help retain material optionally packed into the interior **618**.

Referring to FIG. 17, an implant **700** includes a spacer **702**, a first extension **704**, and a second movable extension **706**. The spacer **702** includes a sidewall **708** defining an outer surface **710** and an inner surface **712**. In the example of FIG. 17, the spacer **702** is generally in the shape of a hollow flattened cylinder with a "D"-shaped cross section. However, the spacer **702** could be any desirable shape. The spacer **702** includes a plurality of openings **714** communicating from the outer surface **710** to the inner surface **712**. The movable extension **706** includes a projection **716** configured generally like the spacer **702** but being sized to slide within the spacer **702** in telescoping relationship. The projection (or the spacer) may optionally include one or more fixation mechanisms to lock the extensions **704**, **706** at a desired longitudinal spacing. Fixation mechanisms may include a set screw **718**, a ridge **720** forming a snap fit with a groove **722** or other feature, a detent **724** engageable with openings **714**, and/or other suitable fixation mechanisms. Any one or combinations of these mechanisms may be used and they may be reversed from the orientation shown.

Referring to FIGS. 18-20, an implant **800** includes a spacer **802**, a first extension **804**, and a second, movable extension **806**. The spacer **802** includes a plurality of cantilevered beams similar to FIGS. 15 and 16 except that in this example there are three beams **808**, **810**, **812**. The beams project parallel to a longitudinal axis **814** away from the first extension **804**. In the example of FIG. 18, the anterior beam **812**

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includes a posteriorly opening groove **816**. The posterior beams **808**, **810** and anterior beam **812** define an elongated slot **818** between them opening superiorly and inferiorly. The posterior beams **808**, **810** further define an elongated slot **820** between them opening posteriorly. FIG. 20 illustrates a cruciform opening **822** defined by the projection of the groove **816** and slots **818**, **820** projected through the first extension **804**. The movable extension **806** includes a body **824** sized to slidably engage the slot **818**. An optional lug **826** can project anteriorly into groove **816** to constrain tilting of the movable extension **806** relative to the first extension **804**. The lug **826** can be sized to fit closely within groove **816** to prevent tilting of the movable extension **806** or it can be sized smaller than the groove **816** to permit a predetermined amount of tilt. A set screw **828** is provided to lock the movable extension **806** to the spacer **802**.

Referring to FIG. 21, an implant **900** is depicted that is configured generally like that of FIG. 16. However, an end wall **902** adjacent the first extension **904** includes a through bore **906** and the movable extension **908** includes a key **910** with a through bore **912**. The bores **906**, **912** receive a fastener to fix the extensions **904**, **908** at a maximum spacing to prevent them from moving apart. Fasteners may include screws, bolts, nuts, cables, wires, ties, rods, and/or any other suitable fastener. In the example of FIG. 21, the fastener includes an elongated crimp receiving member **914**, such as a cable, and crimp members **916**, **918**, such as ferrules or compressible beads.

Referring to FIG. 22, an implant **1000** includes a spacer **1002**, a first extension **1004**, and a second extension **1006**. The spacer **1002** includes an outer surface **1008** defining one or more longitudinal grooves **1010** extending along the outer surface **1008** and through the first extension **1004**. The first extension **1004** includes one or more corresponding slots **1012** having a radially outwardly extending portion **1014** through the first extension **1004** and communicating with the grooves **1010**. The slots **1012** have a radially inwardly extending portion **1016** defining a shoulder **1018** at the end of the grooves **1010**. The second extension **1006** includes one or more corresponding projections **1020** projecting longitudinally toward the first extension **1004** and terminating at a radially inwardly directed tab **1022**. The second extension **1006** further includes a centering bore **1024** having conical opening engageable with a conical free end **1026** of the spacer **1002**. The second extension **1006** is attached to the spacer **1002** by pressing the tabs **1022** against the conical end **1026** of the spacer **1002** to spread the projections outwardly until the tabs **1022** engage the grooves **1010**. The tabs **1022** are slid along the grooves **1010** until they exit through the slots **1012** and the tabs **1022** snap inwardly over the shoulders, **1018** and into the portions **1016**. Abutment of the tabs **1022** against the shoulders **1018** prevents the first and second extensions **1004**, **1006** from moving apart. The engagement of the conical end **1026** of the spacer **1002** with the bore **1024** provides radial stability to the assembly.

Referring to FIG. 23, an implant **1100** includes a spacer **1102**, a first extension **1104**, and a second extension **1106**. The spacer **1102** includes a transverse groove **1108** with a central boss **1110** having an enlarged head **1112**. The second extension **1106** includes a portion **1114** sized to fit within the groove **1108** and an opening **1116** bordered by one or more angled tabs **1118**. The second extension **1112** is assembled to the spacer by pressing the portion **1114** into the groove **1108** with the central boss **1110** directed into the opening **1116**. As the boss **1110** is pressed through the opening **1116**, the tabs **1118** flex outwardly to allow it to pass. Once the boss **1110** is past the tabs **1118**, the tabs **1118** return to their original

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position and snap behind the enlarged head 1112. In this configuration, the boss 1110 retains the second extension 1106 longitudinally and the groove 1108 prevents the second extension 1106 from rotating about the longitudinal axis of the implant 1100.

Referring to FIG. 24, an implant 1200 includes a spacer 1202, a first extension 1204, and a second extension 1206. The spacer 1202 includes a solid cylindrical sidewall 1208 defining a hollow interior 1210. The extensions 1204, 1206 are similarly configured and each includes a projection 1212, 1214 sized to fit inside of the spacer 1202. The extensions 1204, 1206 may attach to the spacer by press-fitting, snap-fitting, screwing, and/or otherwise engaging the projections 1212, 1214 with the spacer 1202. Alternatively, or additionally, the extensions 1204, 1206 may attach to the spacer 1202 with any of the previously depicted attachment mechanisms such as with a setscrew as shown in FIG. 3 or an elongated fastener as shown in FIG. 21. In the example of FIG. 24, the extensions 1204, 1206 are slotted longitudinally to form flexible petals 1216 that press into the spacer 1202. The extensions 1204, 1206 include openings 1218 to allow tissue growth, permit attachment of cerclage members, and/or receive additional fasteners attached to the spinous processes.

The spacer 1202 of FIG. 24 could have openings as shown in some of the other examples. Likewise, the other examples could have a solid surface as shown in FIG. 24. Similarly the extensions of any of the examples may be solid, have openings, or be otherwise advantageously configured.

Implants according to the present invention may be implanted using a variety of surgical approaches and techniques. Surgical approaches may include supraspinous ligament sacrificing posterior approaches, supraspinous ligament preserving posterior approaches, lateral approaches, and/or other suitable approaches. Techniques may include leaving the tissues at the surgical site unmodified or modifying the tissues such as trimming, rasping, roughening, and/or otherwise modifying them. For example, in FIG. 1, a lateral approach is used and the inferior spinous process is cut on its superior surface 26 to enlarge the interspinous space to receive the implant 100. After the interspinous space is prepared, the spacer 102 is inserted into the interspinous space. If a first extension 126 is present it may be pressed inwardly to lie near or abut one or more spinous processes. If a second extension 128 is used, it is engaged with the spacer 102 and also optionally pressed inwardly. In FIG. 1, opposing extensions 126, 128 having inwardly directed bone fasteners have been used and pressed inwardly so that the fasteners 132 engage the spinous processes 20, 21. The engagement of the fasteners 132 with the inferior spinous process 21 is not shown in FIG. 1 because the extensions are offset superiorly and inferiorly as shown in FIGS. 3, 8, and 9.

Referring to FIGS. 25 and 26, a set of instruments 1300 is provided to facilitate lateral insertion of an implant into the interspinous space. The set of instruments includes a plurality of inserters 1302, 1303 in which each inserter 1302, 1303 has a first or handle portion 1304 and a second or working portion 1306. The working portion 1306 is insertable into the interspinous space. Preferably, the handle portion 1304 extends transverse to the working portion 1306 to facilitate holding and manipulating the inserter 1302, 1303 while the working portion 1306 is in the interspinous space. The handle portion 1304 and working portion 1306 may define a curve, angle, offset, and/or any other suitable transverse orientation. In the example of FIG. 25, the inserters 1302, 1303 are generally "L"-shaped. The working portion 1306 tapers from a relatively larger cross-sectional dimension at a first portion 1307 spaced away from its free end 1308 to a relatively smaller

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cross-sectional dimension at its free end 1308. In the illustrative embodiment, the working portion is conical and tapers from a larger diameter to a smaller diameter. The end 1308 defines a hollow tip having an opening 1310. The set of instruments 1300 is provided with a plurality of similarly configured inserters having differently sized working portions 1306 such that the end 1308 of one inserter 1302 will fit inside the opening 1310 at the tip of another inserter 1303. Optionally, the working portion 1306 may be separated into opposing halves attached to opposing handles 1314, 1316. As the opposing handles 1314, 1316 are moved relative to one another, the opposing halves of the working portion 1306 move relative to one another. In the illustrative embodiment, squeezing the handles 1314, 1316 toward one another causes the working portion 1306 to expand as the opposing halves of the working portion 1306 open outwardly away from one another.

In use, a first inserter 1302 is inserted into the interspinous space. The first inserter 1302 is relatively small to ease insertion. As the end 1308 is inserted further, the tapered working portion 1306 expands the interspinous space. Optionally, the interspinous space can be further expanded by expanding the working portion while it is inside the interspinous space such as by squeezing the handles 1314, 1316. A second, larger inserter 1302 is engaged with the first inserter 1303 by placing its hollow tip over the tip of the first inserter 1303 and then passing the overlapping instruments back through the interspinous space to remove the first inserter 1303 and insert the second inserter 1302. As the end of the second inserter 1303 is inserted further, the tapered working portion expands the interspinous space. Optionally, the interspinous space can be further expanded by expanding the working portion while it is inside the interspinous space. Progressively larger inserters can be inserted in this fashion until the interspinous space has been expanded to the desired size. Once the desired size has been reached the appropriate implant size may be determined by noting the size of the last inserter. The inserter may optionally include indicia 1320 on the tapered working end corresponding to different spacer sizes to further facilitate sizing the implant. The implant is inserted by engaging the spacer 1402 with the working end of the inserter as shown in FIG. 26. The implant may be engaged inside of the hollow tip of the inserter or the tip of the inserter may engage a hollow tip on the implant as shown. The spacer 1402 is pressed into the interspinous space as the inserter is withdrawn.

Referring to FIGS. 27-28, a first implant 1500 includes a spacer 1502 and extensions 1504. The extensions are generally planar in the anterior-posterior plane as shown in FIG. 27, and include a superior portion 1506, an inferior portion 1508, and spikes 1510 projecting medially from each of the superior and inferior portions to engage spinous processes superior and inferior to the spacer 1502. The extensions 1504 are mounted to the spacer 1502 to permit the spacing between the extensions to be adjusted such as by surrounding and sliding along a portion of the spacer 1502 and to permit the spacing between the extensions to be locked such as with set screw 1503. A second implant 1520 includes a spacer 1522, extensions 1524, and set screw 1523. The extensions 1524 include a superior portion 1526 and an inferior portion 1528. The inferior portion 1528 is offset laterally (outwardly) relative to the superior portion 1526 to facilitate the inferior portion 1528 overlying the superior portion 1506 of the first implant 1500 in a shingle-like arrangement. In the illustrative example, the superior portion 1526 and inferior portion 1528 define medial surfaces 1530, 1532 lying generally in planes 1534, 1536 that are generally parallel to one another and offset by a distance 1538. The distance 1538 is preferably

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equal to at least the thickness **1540** of the superior portion **1506** of the first implant to allow the inferior portion **1528** of the extension **1524** to lie flat against the superior portion **1506** of the extension **1504**. The offset distance **1538** may be other values that result in an angular engagement of the inferior portion **1528** of the extension **1524** with the superior portion **1506** of the extension **1504**. The offset may be defined by a discreet offset portion **1542** shown as a generally straight portion defining a medial surface **1543** lying generally in a plane **1544** transverse to planes **1534** and **1536**. Alternatively, any one or combination of portions **1526**, **1528**, and **1544**, including surfaces **1530**, **1532**, and **1543** may be flat, curved, or otherwise shaped. Likewise, the offset may be reversed so that the extensions of first implant **1500** overlies the extensions of second implant **1520**.

Preferably, the inferior portion **1528** of extension **1524** includes a medially facing gripping feature and the superior portion **1506** of extension **1504** includes a cooperating laterally facing gripping surface. In the illustrative example of FIG. 27, shown more clearly in FIG. 28, the gripping surfaces include a plurality of conical bristles **1546** able to nest together to resist relative sliding between the extensions **1504**, **1524**. FIG. 29 illustrates an alternative arrangement in which a spike **1548** from one extension engages a hole **1550** in another extension.

In use, the first implant is placed with its spacer between adjacent spinous processes at a first spinal level and the spikes of its extensions engaging the sides of the adjacent spinous processes. A second implant is then placed with its spacer between adjacent spinous processes at a second spinal level and the spikes at one end of its extensions engaging the sides of a spinous process and the other end overlying and engaging the extensions of the first implant.

Referring to FIG. 30, two implants **1570**, **1580** are shown in overlapping relationship. Implant **1570** includes a spacer **1571** and generally planar extensions **1572** having medially facing spikes **1574** and laterally facing sockets **1576**. The extensions **1572** are able to engage the spacer **1571** at variable angles. Implant **1580** likewise includes a spacer **1581** and generally planar extensions **1582** having medially facing spikes **1584** and laterally facing sockets **1586**. The extensions **1582** are able to engage the spacer **1581** at variable angles. The spikes of the extensions of one implant are receivable in the sockets of the extensions of another implant at varying angles from coaxial, or parallel, to angles as high as 45 degrees or higher. In use, one implant is placed with its spacer between adjacent spinous processes at a first spinal level and the spikes of its extensions engaging the sides of the adjacent spinous processes. A second implant is then placed with its spacer between adjacent spinous processes at a second spinal level and the spikes at one end of its extensions engaging the sides of a spinous process and the spikes at another end of its extensions engaging sockets in the extensions of the first placed implant.

In the illustrative example of FIG. 30, no offset is required in the extensions to permit an overlying relationship due to the variable angle between the extensions and the spacers. The implants of FIG. 27 may likewise permit variable angles between extensions and spacers. However, because of the offset of the extensions, the extensions will assume a more parallel orientation. The implants of FIGS. 27-30 may incorporate features of any of the plurality of implants described throughout this specification.

The above described overlying implants facilitate placement of implants at adjacent spine levels by permitting the extensions to overlap and thus the extensions require less space on the sides of the spinous processes. In addition, where

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a rigid connection is formed between overlapping extensions, the rigidity of the overall spinal construct of multiple implants is increased. In the above described overlying implants, opposing surfaces of overlapping extensions may include pads, hooks, pins, teeth, bristles, surface roughness, adhesive, holes, loops, screws, bolts, and/or other features that permit one extension to grip another.

Referring to FIGS. 31-34, an implant **1600** includes a spacer **1602** and extensions **1604**. As best seen in FIG. 32, the spacer **1602** is shaped to provide superior and inferior voids or openings **1602V**. The voids or openings **1602V** are similar to the openings described throughout the application. The extensions **1604** include medially facing spikes **1606** for engaging the vertebrae. The spacer **1602** has a length **1608** extending medially-laterally and a height **1610** extending superiorly-inferiorly. A cylindrical path **1612** extends through the spacer **1602** along its length. The cylindrical path **1612** opens posteriorly through a slot **1614**. A draw bolt **1616** has a spherical tip **1618** at a first end and a cylindrical threaded portion **1620** at a second, opposite end. The tip **1618** and threaded portion are connected by a neck **1622**. The extensions **1604** include threaded bores **1624** formed through the extensions **1604** in an anterior-posterior direction. The implant **1600** is assembled by threading the draw bolt **1616** into the extensions **1604** with the tip **1618** projecting anteriorly. The tip is slidably engaged with the path **1612** in the spacer **1602** with the neck projecting through the slot **1614**. As can be appreciated with reference to FIG. 32, the spherical tip **1618** is shown in the cylindrical path **1612**. Moreover, the neck **1622** is shown extending from the tip **1618** through the slot **1614**.

In use, the spacer **1602** is placed between adjacent spinous processes and the extensions **1604** are engaged with the spacer **1602**. Alternatively, one or both extensions **1604** may be preassembled to the spacer before the spacer **1602** is inserted between adjacent spinous processes. The extensions **1604** are pressed together to engage the spikes **1606** with the spinous processes. The fit of the spherical tip **1618** of the draw bolt **1616** within the cylindrical path **1612** permits the extensions **1604** to be angled relative to the spacer **1602**. If the neck **1622** of the draw bolt **1616** fits closely within the slot **1614**, the extensions are constrained to angulate medially-laterally. If the neck **1622** of the draw bolt **1616** fits loosely within the slot **1614**, the extensions may angle both medially-laterally and superiorly-inferiorly. The angulation of the extensions permits them to adjust to the angle of the underlying bone. Each draw bolt **1616** is then rotated to move the corresponding extension **1604** toward the spacer **1602** until the extension **1604** abuts the spacer **1602**. Further rotation of the draw bolt presses the extension **1604** and spacer **1602** together to lock their relative positions.

In the illustrative example of FIGS. 31-34, the extensions **1604** are flared outwardly at an inferior portion **1626**. In particular, and perhaps best seen in FIG. 31 in one exemplary embodiment, a first of the extensions **1604** may be considered to have a first planar surface **1604'** defined by the superior portion **1604S**. Further, the first of the extensions **1604** may be considered to have a second planar surface **1604''** defined by the inferior portion **1604I**. A second of the extensions **1604** similarly may be considered to have a third planar surface **1604'''** and a corresponding fourth planar surface **1604''''**. As can be appreciated by FIG. 31, the first planar surface **1604'** and the second planar surface **1604''** are non-coplanar with each other. Similarly, the third planar surface **1604'''** and the fourth planar surface **1604''''** are non-coplanar with each other. The outward flare directs the superior spikes outwardly and inwardly to accommodate a small or missing

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spinous process such as, for example, on the sacrum of a patient. The inferior portion may include one or more holes **1628** to receive screws **1630** that seat on the inferior portion and engage the inferior vertebra, such as, for example, the sacrum to more positively engage the inferior vertebra.

Referring to FIGS. **35-36**, an implant **1700** includes a first half **1702** and a second half **1704**. Each half **1702**, **1704** includes both a portion of a spacer **1706** and an extension **1708**. At least one of the spacer portions includes a medial-lateral slot **1710** and at least one of the extensions includes a superior-inferior slot **1712**. When assembled, the slots **1710**, **1712** overlies one another and a bolt **1714** extends through the slots to pin the first and second halves **1702**, **1704** together. A nut **1716** captures the bolt **1714**. The superior-inferior slot **1712** permits adjustment of the superior-inferior spacing between the spacer portions **1706** to vary the spacer height as can be seen by comparing FIGS. **35** and **36**. The medial-lateral slot **1710** permits adjustment of the medial-lateral spacing between the extensions **1708** to allow the extensions to be engaged with the spinous processes. When the desired spacings are achieved, the nut **1716** is tightened to compress the assembly together and simultaneously lock both of the spacings. In the illustrative example of FIGS. **35-36**, the inferior portion **1718** of at least one of the extensions has angled spikes arranged to engage an inferior vertebra with a small or missing spinous process such as the sacrum. In this example, one extension has spikes superiorly and inferiorly while the other extension is smooth to ease height adjustment.

Referring to FIGS. **37-38**, a modular implant **1800** includes a cross bar **1802** and extensions **1804**. Each extension **1804** includes a spiked pad **1806** with spikes **1807** projecting outwardly from the spiked pad, a spinous process shelf **1808** projecting outwardly in the same direction as the spikes **1807**, and an extension rod **1810**. The spiked pad **1806** has a width **1811** and the spinous process shelf **1808** has a width **1812**. In the illustrative example of FIGS. **37-38**, the spinous process shelf width **1812** is less than the spiked pad width **1811** to permit assembly of aligned, opposing extensions **1804** with spinous process shelves **1808** lying side-by-side in the same plane. Further, in the illustrative example of FIGS. **37-38**, the spinous process shelf width **1812** is less than one-half the spiked pad width **1811** to permit assembly of aligned, opposing extensions **1804** with spinous process shelves **1808** lying side-by-side in the same plane with a gap between them to permit tissue growth between the shelves. A joint cylinder **1813** includes a threaded axial bore **1814** along the longitudinal axis of the joint cylinder and multiple transverse bores transverse to the axial bore **1814** and extending through the joint cylinder **1813** sidewall. The transverse bores include an inboard transverse bore **1816** and outboard transverse bores **1818** on either side of the inboard transverse bore **1816**. The inboard transverse bore **1816** is sized to receive the cross bar **1802** in close fitting sliding relationship. The outboard transverse bores **1818** are sized to receive the extension rods **1810** loosely to permit the extension rods **1810** to toggle in the bores.

The modular implant **1800** is assembled by placing a joint cylinder **1813** on each end of a cross bar **1802** with the cross bar **1802** extending through the inboard bore **1816** of each joint cylinder **1813**. Two cross-drilled balls **1820** are next inserted into the axial bore **1814** of each joint cylinder **1813** and aligned with the outboard bores **1818**. Two extensions are mounted to each joint cylinder **1813** by inserting the extension rod **1810** of each extension into the outboard bores **1818** and through the corresponding cross-drilled ball **1820**. The cross-drilled balls **1820** are sized to fit closely within the axial bore **1814** and touch the cross bar **1802**. Once assembled, the

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modular implant **1800** can be adjusted by sliding and rotating the joint cylinders **1813** relative to the cross bar **1802** and sliding, rotating, and toggling the extension rods **1810** relative to the joint cylinders **1813**. When the desired adjustment is achieved, a set screw **1822** is inserted into at least one side of each axial bore **1814** and tightened to compress the cross-drilled balls **1820**, extension rods **1810**, and cross bar **1802** tightly together and thereby lock the adjustment. In the illustrative example of FIGS. **37-38**, the extensions **1804** are all identical, the cross-drilled balls are identical, and the joint cylinders are identical so that an implant can be assembled from a few basic components simplifying assembly and reducing inventory costs. However, if desired, a wider variety of component shapes and sizes may be provided to allow the modular implant to be tailored in various ways.

For example, in FIG. **39**, a double ended extension **1824** is provided having an extension rod **1826** extending superiorly and another extension rod **1828** extending inferiorly. By using the double ended extension **1824** as a joiner, the modular implant can be assembled to treat multiple adjacent spinal levels. In the illustrative example of FIG. **39**, the implant has been assembled using the double ended extension **1824** to engage three adjacent spinous processes and thus treat two adjacent spinal levels. However, any number of extensions can be assembled in this manner to treat any number of spinal levels. In addition to components, such as the double ended extension **1824**, to allow treatment of multiple levels, component may be provided that are adapted to particular bone geometries. For example, extensions having flared spiked pads, extra long spikes, and screw receiving holes similar to the examples of FIGS. **31-36** may be provided, for example, to permit assembly of an implant with an inferior portion suitable for gripping a vertebra with a small or missing spinous process, such as, for example, the sacrum.

Referring to FIG. **40**, an implant **1900** similar to that of FIGS. **37-39** is illustrated. The implant **1900** includes extensions **1902** having flattened spikes **1904**.

Referring to FIGS. **41-42**, an implant **1950** similar to those of FIGS. **37-40** is illustrated. However, in the illustrative example of FIGS. **41-42**, the extension **1952** includes an extension rod **1954** and spiked pads **1956** mounted for translation and rotation along the extension rod **1954**. Each spiked pad **1956** is mounted to an extension rod **1954** with a cross drilled sphere **1958** and a split yoke **1960**. The cross drilled sphere **1958** is slipped over an end of the extension rod **1954** and a first end of the split yoke **1960** is snapped over the cross-drilled sphere **1958** so that the cross-drilled sphere **1958** rides in a groove **1962** inside the split yoke **1960**. A second end of the split yoke **1960** is mounted in a bore **1964** in the spiked pad **1956**. The outer surface of the split yoke **1960** includes a tapered portion **1966** adjacent the mounting of the split yoke **1960** in the bore **1964**. The extension rod **1954** is mounted to the cross bar **1968** with joint cylinders **1970** similar to those of the examples of FIGS. **37-40**. When the joint cylinders **1970** are slid medially to engage the spiked pads **1956** with the spinous processes, each spiked pad **1956** is pressed outwardly toward the extension rod **1954**. The edges of the bore **1964** slide against the tapered surface **1966** and squeeze the split yoke **1960** closed so that it is compressed around the cross-drilled sphere **1958** and extension rod **1954** and locks the relative position of the spiked pad **1956** and extension rod **1954**. Referring to FIG. **43**, an implant **2000** includes spiked pads **2002**, extension rods **2004**, and cross bars **2006**. Each spiked pad **2002** has a spiked face **2008** and an opposite side **2010** having at least one spherical socket **2012** formed in it. In the illustrative example of FIG. **43**, each spiked pad **2002** has two spherical sockets **2012**

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to permit multi-level constructs as described below. Each extension rod **2004** includes a spherical ball end **2014** formed at each of its ends. The cross bar **2006** includes a longitudinal slot **2016** dividing the cross bar **2006** into two cantilevered beams **2018** joined at a first end **2020** and threaded at a second end **2022** for receiving a retaining nut **2024**. The implant **2000** is assembled by snapping a spiked pad **2002** onto each end or each of two extension rods **2004** and placing the extension rods **2004** in the slot of the cross bar **2006**. The nut **2024** is threaded onto the end of the extension rod and threadingly advanced to move the extension rods **2004** closer together and compress the spiked pads against the spinous processes. Additional spinal levels may be accommodated by snapping additional extension rods into the second holes of spiked pads, snapping additional spiked pads **2002** to the free end of the additional rods and compressing the additional assembly with an additional cross bar and nut as shown in FIG. **43**.

Referring to FIG. **44**, an implant **2100** includes a spacer **2102** including a superior bar **2104**, and inferior bar **2106**, and anterior bar **2108**, and a posterior bar **2110**. Gaps **2112**, or fenestrations, between the bars permit tissue growth between the bars and receive extension rods **2114** extending from spiked pads **2116**. In the illustrative example of FIG. **44**, four independent spiked pads **2116** are provided. Two of the spiked pads **2116** are supported by insertion of their extension rods **2114** between posterior surfaces **2118** of the superior and inferior bars and an anterior surface **2120** of the posterior bar. Two of the spike pads **2116** are supported by insertion of their extension rods **2114** between anterior surfaces **2122** of the superior and inferior bars and a posterior surface **2124** of the anterior bar. A bolt **2126** extends from the anterior bar **2108** through a bore **2128** in the posterior bar **2110** and is secured with a nut **2130**. Tightening the nut **2130** compresses the bars and extension posts together to lock the position of the spiked pads **2116**. Loosening the nut **2130** allows independent adjustment of each spiked pad **2116** medially-laterally **2132**, superiorly-inferiorly **2134**, angularly **2136**, and rotationally **2138**.

Referring to FIGS. **45-47**, a portion of an implant **2200** is shown to illustrate a mechanism for providing an adjustable height spacer **2202** having a superior bar **2204** and an inferior bar **2206**. The **2204**, **2206** bars include longitudinal serrations on their anterior sides **2208** and posterior sides **2210**. The bars **2204**, **2206** are received in a first superiorly-inferiorly elongated slot **2212** formed in an extension **2214**. The first slot **2212** includes anterior serrations **2216** engageable with the anterior serrations **2208** of the bars **2204**, **2206** to support the bars in a selected superior-inferior position. A second superiorly-inferiorly elongated slot **2218** is formed in the extension **2214** transverse to the first slot **2212**. The second slot **2218** includes opposed hemi-cylindrical threaded concavities **2220** formed in its sidewalls and directed toward the first slot **2212**. The second slot **2218** receives a lock block **2222** in sliding relationship toward the first slot **2212** and the threaded concavities **2220** receive a lock screw **2224** in threaded relationship. The lock block **2222** includes anterior facing serrations **2223** engageable with the posterior serrations **2210** of the bars **2204**, **2206**. In use, the bars **2204**, **2206** and extension **2214** are engaged with the bars **2204**, **2206** received in the first slot **2212**. The bars **2204**, **2206** are adjusted superiorly-inferiorly and medially-laterally within the first slot **2212** to a desired position relative to the extension **2214**. The lock screw **2224** is then rotated causing the lock screw to advance toward the first slot **2212** and drive the lock block **2222** toward the first slot **2212**. The lock block **2222** presses against the bars **2204**, **2206** causing the serrations of the lock block **2222**, bars **2204** and **2206**, and first slot **2212** to engage and lock the

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desired relative position between the extension **2214** and rods **2204**, **2206**. Alternatively, the serrations may be omitted and locking accomplished by frictional engagement.

The mechanism of FIG. **44** may be substituted in the preceding examples. For example the mechanism of FIG. **44** may be substituted in the implant **100** of FIGS. **1-9** to provide implant **100** with an adjustable height spacer.

Referring to FIGS. **48-49**, an implant **2300** suitable for treating multiple spinal levels includes multiple spacers **2302**, **2304** and first and second unitary, multilevel extensions **2306**. Each spacer includes an elongated, hollow, body having a non-circular cross-sectional shape (FIG. **49**). Each spacer further includes at each end a first slot **2310** formed through its sidewall and extending a short distance longitudinally toward the opposite end of the spacer to an inboard end of the first slot. Each spacer further includes a second slot (not shown) formed through its sidewall and extending circumferentially from the inboard end of each first slot **2310** to a third slot **2312**. In the illustrative example of FIGS. **48-49**, the first slot **2310** is formed in a relatively narrow side **2314** of the non-circular spacer and the third slot **2312** is formed in a relatively wide side **2316** of the non-circular spacer, the sides being approximately ninety degrees apart (FIG. **49**). A cylindrical nut **2318** is provided to fit inside the hollow body at each end of each spacer **2302**. The nut **2318** includes a threaded cross-bore **2320**. The extensions **2306** each include a generally flat, medially facing surface **2322** having multiple spiked regions **2324**, **2326**, **2328** and a flange **2330** extending laterally from the extension **2306**. Each flange **2330** includes superiorly-inferiorly elongated holes **2332** extending through the flange **2330** from a posterior surface **2334** to an anterior surface **2336**. Lock bolts **2338** are provided to join the extensions **2306** to the spacers **2302**, **2304**. In use, the lock bolts **2338** are extended through the flanges **2330** and a nut **2318** is loosely threaded onto each bolt. The spacers **2302**, **2304** are placed between adjacent spinous processes initially with their narrow dimension opposing the spinous processes as shown with the superior spacer **2302** in FIG. **49**. The extensions **2306** are positioned on opposite sides of the spinous processes and the nuts **2318** are slipped into the hollow interior of the spacers with the bolts **2338** sliding through the first slot as shown with the superior spacer **2302** in FIG. **49**. The elongated holes **2332** in the flanges **2330** permits superior-inferior adjustment of the spacers **2302**, **2304** relative to the extensions **2306**. The spacers **2302**, **2304** are then rotated to position their wide dimension opposing the spinous processes as shown with the inferior spacer **2304** in FIG. **49**. This rotation may be accomplished for example by engaging an instrument with the first slit to apply a torque to the spacer. Rotation of the spacers **2302**, **2304** causes the spinous processes to move apart as the wide dimension of the spacers is rotated between the spinous processes. As the spacers rotate, the bolts **2338** slide through the second slot (not shown) until they are aligned with the third slot **2312** in the spacer. The extensions **2306** are now compressed medially to engage the spikes with the spinous processes. The bolts **2338** slide within the third slot **2312** during compression. Once the bolts move inward of the second slots, the spacers are prevented from rotating back by the bolts **2338** abutting the sides of the third slot **2312**. The bolts **2338** are tightened to lock the position of the spacers **2302**, **2304** relative to the extensions **2306**.

While a specific illustrative example and use of implant **2300** has been shown and described, it is to be understood that implant **2300** can be assembled in any order. For example, the nuts **2318** may first be slipped into the spacers **2302**, **2304**, the spacers placed between the spinous processes in a desired final position, the extensions **2306** compressed medially into

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the spinous processes, and then the bolts **2338** inserted and tightened. Likewise, while implant **2300** has been shown to treat two spinal levels, it can be readily modified to treat one, three, four, five or any number of spinal levels. Likewise, while the spacers **2302**, **2304** have been shown with two different dimensions and being rotated to facilitate distraction of the spinous processes, the spacers **2302**, **2304** may be inserted without rotation and may have, for example, a single slot for receiving bolts **2338**.

Referring to FIGS. **50-51**, an implant **2400**, similar to that of FIGS. **1-9**, further includes a separate member **2402**, **2403** engageable with the spacer **2404** to be positioned between adjacent vertebrae. The separate member **2402**, **2403** may be used to provide additional structural support, to provide bone growth promoting material, or both. The member **2402**, **2403** may be made of metal, plastic, bone, ceramic, or any other suitable material. For example, the member **2402**, **2403** may be a structural bone graft that both contributes to the support of the spacing between adjacent vertebrae and provides bone growth promoting minerals and scaffolding to the surgical site. Also, for example, the member **2402**, **2403** may be coupled to the spacer to provide additional material anterior of the spacer. The member **2402**, **2403** may be sized smaller (superiorly-inferiorly) than the spacer **2404** so that it bears little, if any of the load of adjacent vertebrae. Or, the member **2402**, **2403** may be sized similarly to the spacer **2404** so that it shares the load of adjacent vertebrae. Or, the member **2402**, **2403** may be sized larger than the spacer **2404** so that it bears most, or all, of the load of adjacent vertebrae. For example, the member **2402**, **2403** may be a structural allograft bone member that is sized slightly larger than the spacer **2404** to bear the load of adjacent vertebrae to encourage bone growth. However, if the member **2402**, **2403** were to resorb or subside, the adjacent vertebrae would then be safely supported by the spacer **2404**. Referring to FIG. **50**, the member **2402** is generally in the form of a plate-like body having a superior surface **2406**, an inferior surface **2408**, a convex anterior surface **2410**, and generally flat posterior surface **2412** and a posteriorly projecting connecting member **2414**. The connecting member includes a base **2416** joined to the posterior surface **2412** tapering to a neck **2418** connected to an expanded engagement end **2420**. The engagement end **2420** has a cross-sectional shape corresponding to the cross sectional shape of the interior **2422** of the spacer **2404**. In use, the member **2402** is coupled to the spacer **2404** by sliding the engagement end **2420** into the interior **2422** of the spacer **2404**, with the neck **2418** sliding within an anteriorly opening slot **2424** of the spacer **2404**. While the member **2402** is shown in use to augment the anterior side of the spacer **2404**, it may be configured to augment any one or multiple sides of the spacer **2404**.

Referring to FIG. **51**, the member **2403** is similar to member **2402** of FIG. **50** except that instead of engaging the interior of the spacer **2404** it engages the exterior of the spacer **2404** with a ring-shaped engagement member **2450** that slides over the spacer **2404**. In addition, the member **2403** includes chamfers **2452** at each end to provide clearance for portions of the vertebrae such as, for example, the facet joints.

Referring to FIGS. **52-53**, a set **2600** of instruments for distracting or compressing adjacent vertebrae away from or toward one another and for compressing implant extensions medially toward the spinous processes is illustrated. The set **2600** includes a pair of Kocher-style bone clamps **2602** having a scissor-like action with a handle end **2604** and a working end **2606** terminating in bone gripping tips **2608**. A Caspar-style compressor/distracter **2610** includes arms **2612** joined by a rack **2614** extending from one arm and engaging a gear

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assembly **2616** mounted on another arm. A knob **2618** is responsive to rotation to rotate a pinion (not shown) relative to the rack **2614** and cause the rack to translate. Rotation of the knob **2618** in a first direction causes the arms **2612** to move away from one another and rotation of the knob **2618** in an opposite direction causes the arms **2612** to move toward one another. The arms **2612** terminate in arm clamps **2620** able to receive the Kocher-style bone clamps **2602**. The set **2600** further includes implant compressors **2624** having a scissor-like action with a handle end **2626** and a working end **2628** terminating in implant gripping tips **2630**.

In use, an implant **100** is positioned with spacer between adjacent spinous processes **2650** and extensions on each side of the spinous processes **2650**. The bone clamps **2602** are clamped to the vertebrae. For example, they are clamped to adjacent spinous processes **2650**. The arm clamps **2620** of the compressor/distracter are attached to the bone clamps **2602**. The knob **2618** is then rotated to compress or distract the arms **2612**, and by extension the bone clamps **2602**, until the vertebrae are in a desired relative spacing. The implant compressors **2624** are then engaged with the implant **100** and compressed to cause the extensions of the implant to engage the spinous processes to secure the desired spacing between the vertebrae.

Referring to FIGS. **54-56**, an alternative tip configuration **2700** for the implant compressor **2624** of FIGS. **52-53** is illustrated. The tips **2700** include extensions **2702** having a profile contoured to generally match the posterior profile of the implant extensions **2704** to distribute compressive forces over the surface of the implant extensions **2704**. The compressor extensions **2702** taper toward their superior and inferior aspects **2706**, **2708** to minimize the space needed superiorly and inferiorly for tip insertion and to decrease the amount of the surgical view that is obstructed by the tips. Where the implant includes a set screw bore **2710**, the extension **2702** and arm **2710** may include a relieved portion **2712** aligned with the set screw bore **2710** to permit driving a set screw in the bore **2710**.

Referring to FIG. **57**, an implant inserter **2800** is useful for inserting an implant **100** similar to that of FIGS. **1-9** in a direct posterior approach. The inserter **2800** includes a first arm **2802** and a second arm **2804** joined in a scissor-like arrangement and having a handle **2806** end and a working end **2808**. The working end of each arm **2802**, **2804** includes a clamping face **2810**, **2812** movable toward and away from one another in response to movement of the working end of the arms toward and away from one another. The clamping faces **2810**, **2812** are operable to clamp, and thereby grip, the first extension **126** of the implant **100**. The first arm **2802** includes a foot **2814** projecting medially from first end **2816** near the clamping faces **2810**, **2812** to a second end **2818** spaced from the clamping faces **2810**, **2812**. The foot **2814** is positionable over the spacer **102** when the clamping faces **2810**, **2812** are in clamping engagement with the first extension **126**. A slot **2820** is formed near the second end **2818** of the foot **2814** and extends posteriorly from an anterior edge **2822** of the foot **2814**. The slot **2820** is sized to receive the second extension **128**.

In use, the second extension **128** is placed on the spacer **102** and the inserter **2800** is engaged with the implant by positioning the foot over the spacer **102** such that the slot **2820** receives the second extension **128** and the clamping faces **2810**, **2812** are on opposite sides of the first extension **126**. The inserter handles **2806** are operated to clamp the first extension **126**. Thus clamped, the first and second extensions **126**, **128** are held securely in a predetermined spaced relationship. If desired, the set screw **130** (FIG. **3**) may be inserted

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and tightened to further secure the second extension **128** in anticipation of eventual removal of the inserter **2800**. A relief cut **2824** through the foot **2814** posteriorly-to-anteriorly is aligned with the set screw bore to facilitate operation of the set screw while the implant **100** is engaged with the inserter. The inserter **2800** may be used to insert the implant **100** in a direct posterior-to-anterior direction between adjacent spinous processes. The superior and inferior aspects **2826**, **2828** of the foot **2814** may be relieved to avoid tissue impingement on the foot **2814** and to improve visualization.

Referring to FIG. **58**, a rasp **2900** is provided for rasping adjacent tissues, for example, for removing tissue between adjacent spinous processes in preparation for insertion of the implant **100**. The rasp **2900** includes head **2901** having a conical tip **2902** to aid insertion and teeth **2904**, insertion and removal of the rasp head **2901** along its longitudinal axis and rotation of the rasp head **2901** about its longitudinal axis **2906** will remove abutting tissue. In the case of its use to prepare adjacent spinous processes, an angled handle **2908**, for example forming an angle **2910** in the range of 135 to 45 degrees, more preferably in the range of 120 to 60 degrees, more preferably at about 90 degrees, is useful to position the head **2901** between the spinous processes and rotate it back and forth about its axis to abrade tissue. The teeth **2904** are angled toward the handle **2908** to ease the initial insertion of the head **2901**. The angled teeth **2904** are less prone to snagging upon insertion.

Although examples of a spinous process implant and associated instruments and techniques have been described and illustrated in detail, it is to be understood that the same is intended by way of illustration and example only and is not to be taken by way of limitation. Accordingly, variations in and modifications to the spinous process implant, instruments, and technique will be apparent to those of ordinary skill in the art, and the following claims are intended to cover all such modifications and equivalents.

What is claimed is:

1. An implant for placement between spinous processes of adjacent vertebrae of a spine, the implant comprising:

a spacer with a first end, a second end, and a longitudinal axis extending from the first end to the second end, the spacer having a sidewall extending longitudinally and having superior and inferior surfaces operable to abut the spinous processes and maintain the spinous processes in spaced apart relationship, the superior and inferior surfaces being spaced apart a distance corresponding to a predetermined minimum spacing between the spinous processes, the spacer having a length extending medially-laterally and a height extending superiorly-inferiorly such that the spacer further includes:

a cylindrical path extending along the length, the cylindrical path defining a cylinder with a circular cross-sectional shape,

a slot opening posteriorly on the cylindrical path, and

a bolt including a spherical tip slidably disposed within the cylindrical path and a threaded shaft extending from the slot; and

a first extension projecting from the spacer transverse to the longitudinal axis to lie generally alongside the spinous processes of adjacent vertebrae, wherein a superior portion of the first extension forms a first surface facing a superior spinous process and an inferior portion of the first extension forms a second surface facing an inferior spinous process such that the second surface is non-coplanar with the first surface, the first extension being engageable with the spinous processes to limit the maximum spacing between the spinous processes, the first

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extension including a threaded bore, such that the first extension is connected to the spacer by threading the bolt into the threaded bore.

2. The implant of claim 1, further comprising at least one fastener on the inferior portion of the first extension wherein the second surface of the inferior portion is adapted to direct the at least one fastener into bone.

3. The implant of claim 1, further comprising at least one fastener and wherein the second surface of the inferior portion comprises a bore such that the at least one fastener is removably coupled to the bore and adapted to engage bone.

4. The implant of claim 3, wherein the fastener comprises a bone screw.

5. The implant of claim 4, wherein the bone screw is adapted to engage the sacrum.

6. The implant of claim 1, further comprising a plurality of fasteners wherein at least one of the plurality of fasteners resides on the second surface of the inferior portion and at least one of the plurality of fasteners resides on the first surface of the superior portion such that the at least one fastener residing on the second surface is angled and non-parallel with the at least one fastener residing on the first planar surface, and wherein the first surface and the second surface are adapted to direct the plurality of fasteners into bone.

7. The implant of claim 2, wherein the at least one fastener is adjustable angularly relative to the second surface of the inferior portion of the first extension such that the at least one fastener is non-normal with the second surface of the inferior portion.

8. The implant of claim 1, wherein the superior portion and the inferior portions are offset anteriorly-posteriorly relative to one another to define a generally "Z"-shaped offset such that the inferior portion extends further posteriorly than the superior portion extends anteriorly.

9. The implant of claim 1, further comprising a second extension opposing the first extension wherein the second extension is adapted to lie generally alongside the spinous processes of adjacent vertebrae on an opposite side of the first extension.

10. The implant of claim 9, wherein the second extension directly engages the spacer and is translated over the spacer toward the first extension.

11. The implant of claim 9, wherein the second extension comprises a superior portion forming a third surface and an inferior portion forming a fourth surface such that the fourth surface is non-coplanar with the third surface.

12. The implant of claim 1, wherein the second surface is substantially perpendicular to the longitudinal axis.

13. The implant of claim 1, wherein the first surface is substantially perpendicular to the longitudinal axis.

14. The implant of claim 1, wherein the superior portion and the inferior portion are coupled by a portion of the first extension extending between the superior portion and the inferior portion.

15. An implant for placement between spinous processes of adjacent vertebrae of a spine, the implant comprising:

a spacer with a first end, a second end, and a longitudinal axis extending from the first end to the second end, the spacer having a sidewall extending longitudinally and having superior and inferior surfaces operable to abut the spinous processes and maintain the spinous processes in a spaced apart relationship, at least a first superior opening in the spacer and at least a first inferior opening in the spacer the superior and inferior surfaces being spaced apart a distance corresponding to a prede-

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terminated minimum spacing between the spinous processes, the spacer further including:

a cylindrical path extending along the length, the cylindrical path defining a cylinder with a circular cross-sectional shape,

a slot opening posteriorly on the cylindrical path, and

a bolt including a spherical tip slidably disposed within the cylindrical path and a threaded shaft extending from the slot;

a first extension attached to the spacer, the first extension including a threaded bore, such that the first extension is connected to the spacer by threading the bolt into the threaded bore.

16. The implant of claim 15, further comprising a second extension attached to the spacer and engageable with the spinous processes to limit a maximum spacing between the spinous processes, the first and second extensions each including a superior portion and an inferior portion, the superior portion of the first extension defining a first plane and the inferior portion of the first extension defining a second plane non-coplanar to the first plane, the superior portion of the second extension defining a third plane and the inferior portion of the second extension defining a fourth plane non-coplanar to the third plane, wherein the inferior portion of the second extension diverges from the inferior portion of the first extension in an inferior direction.

17. The implant of claim 15, further comprising a second extension attached to the spacer, the first and second extensions each including a superior portion and an inferior portion, the inferior portions of the first and second extensions each including at least one fastener, wherein the inferior portions are adapted to direct the at least one fastener into bone.

18. The implant of claim 15, wherein at least one of the first superior opening and the first inferior opening includes a transverse passageway through the spacer.

19. The implant of claim 18, wherein the spacer is substantially hollow and the transverse passageway is formed by the hollow spacer.

20. The implant of claim 17, wherein the at least one fastener on the inferior portion of the first extension and the at least one fastener on the inferior portion of the second extension converge.

21. The implant of claim 15, further comprising a second extension attached to the spacer, the first and second extensions each including an inferior portion, wherein the inferior portions of the first and second extension are adapted to engage a sacrum.

22. The implant of claim 15, further comprising a second extension attached to the spacer, the first and second extensions each including an inferior portion, wherein the inferior portions of the first and second extensions are adapted to engage a bone having a small spinous process relative to an adjacent spinous process.

23. The implant of claim 15, further comprising a second extension attached to the spacer, the first and second extensions each including an inferior portion, wherein the inferior portions of the first and second extensions are adapted to engage a lamina.

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24. A method of treating spine disease comprising:

providing a spacer with a first end, a second end, and a longitudinal axis extending from the first end to the second end, the spacer having a sidewall extending longitudinally and having superior and inferior surfaces operable to abut adjacent spinous processes and maintain the spinous processes in a spaced apart relationship, the superior and inferior surfaces being spaced apart a distance corresponding to a predetermined minimum spacing between the spinous processes; a first extension projecting from the spacer transverse to the longitudinal axis to lie generally alongside the spinous processes of adjacent vertebrae, the first extension having a threaded bore, a superior portion and an inferior portion where part of the inferior portion is angled and non-parallel with respect to the superior portion, the first extension being engageable with the spinous processes to limit the maximum spacing between the spinous processes; and a second extension to lie generally alongside the spinous processes of adjacent vertebrae on a side opposite the first extension, the second extension having a superior portion and an inferior portion where part of the inferior portion is angled and non-parallel with respect to the superior portion, the second extension being engageable with the spinous processes to limit the maximum spacing between the spinous processes, the spacer having a length extending medially-laterally and a height extending superiorly-inferiorly such that the spacer further includes:

a cylindrical path extending along the length, the cylindrical path defining a cylinder with a circular cross-sectional shape,

a slot opening posteriorly on the cylindrical path, and

a bolt including a spherical tip slidably disposed within the cylindrical path and a threaded shaft extending from the slot;

inserting the spacer between spinous processes of adjacent vertebrae to provide both an extension stop and a flexion stop;

engaging the second extension to the spacer;

threading the bolt into the threaded bore;

translating the second extension axially towards the first extension so as to slide the second extension toward the first extension so the first and second extensions engage with the spinous processes to fix the spacer to the spinous processes; and

securing the second extension at a desired location along the spacer relative to the first extension.

25. The method of claim 24, wherein the spacer further comprises a plurality of fasteners wherein at least one of the plurality of fasteners resides on the part of the inferior portion of the first extension and at least another of the plurality of fasteners resides on the part of the inferior portion of the second extension, and wherein the translating step comprises engaging the at least one and the at least another of the plurality of fasteners with a sacrum.

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